EXHIBIT T

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

- x

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

- x

THIS DOUCMENT RELTES TO:
DIANNE M. BELLEW

Plaintiff

v. Case No. 13-cv-22473

ETHICON, INC., et al.

Defendants

- x

DEPOSITION OF HOWARD C. JORDI, PH.D.

Tuesday, August 19, 2014

9:03 a.m.

Jordi Labs, LLC

200 Gilbert Street

Mansfield, Massachusetts

Michelle Keegan, Court Reporter

APPEARANCES:

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EXHIBITS

EXHIBITS (continued)

PROCEEDINGS

HOWARD C. JORDI, PH.D.,

having been satisfactorily identified and duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION

BY MR. THOMAS:

Q. Good morning, Dr. Jordi.

A. Good morning.

Q. How are you today?

A. Good. Thank you.

Q. Good. Dr. Jordi, I've had the pleasure of taking your deposition before. Correct?

A. Yes, you have.

Q. And that was in the Lewis case?

A. Yes.

Q. And a number of the exhibits, meshes, that you analyzed in the Lewis case are a part of your report in both the Bellew case and the New Jersey consolidated case. Correct?

A. Correct.

Q. It's my goal and my representation to the plaintiffs that I will not ask questions about Lewis and Batiste that I could have asked before at your prior deposition, and I will endeavor to do that.

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Please be patient with me because there will be times when I have to refer to that testimony as a predicate for questions I'm going to ask you about the Bellew case and the New Jersey case. Fair enough?

A. Yes, sir.

Q. And there may be times that Mr. Thornburgh wants to discuss that with me before he lets you answer the question. And if you'll just be patient with us, we'll work through it in an effort to get the best answers we can. Fair enough?

A. Fair enough.

MR. THOMAS: These depositions are in two cases. One is on the Bellew case, which is an MDL case pending before Judge Goodwin, in the Southern District of West Virginia. The second case I know as the New Jersey consolidated cases. And the report I have by Dr. Jordi is dated May the 20th, 2014.

Q. Have I accurately described the two reports that we're here to talk about today?

A. I believe so.

MR. THOMAS: I'm going to mark the Bellew expert report as Jordi Number 1 and the New Jersey expert report as Jordi Number 2.

(Exhibit Numbers 1 and 2 marked for identification)

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Q. And I will tell you that, in going through the Bellew expert report, I found out that for whatever reason my color copier computer was unable to copy page 20 of your report.

A. Of the Bellew?

Q. Of the Bellew report. Just so you know, those are the images of the -- photographic images of the explants, I think.

A. Would you like a copy?

Q. I have a copy. Do you have one? I just don't have one in this exhibit. I want to make sure that the record is clear that this exhibit is missing page 20 because I couldn't get it to copy for whatever reason.

A. I can make a copy right now and you can put it in if you want. It just takes a second.

Q. We'll do it later. I have a limited amount of time.

And you have some documents in front of you. What do you have in front of you?

A. Bellew report.

Q. Okay. Do you have a copy of your New Jersey report in front of you?

A. I don't believe I do. No, I don't.

Q. Okay. What --

A. Do you want me to get one?

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MR. THORNBURGH: He's got copies.

Q. What other documents do you have in front of you?

A. Ethicon document dated November 5th, 1984.

Do you want ETH MESH numbers?

Q. Is that a category of documents, if you will? How would you describe the documents that you have in front of you?

A. ETH MESH documents of studies done by Ethicon scientists in the '84 time frame.

Q. Are the documents that you have in front of you the documents that are recently added to your reliance list?

A. I believe so, yes.

Q. Okay. Did you bring your file with you to the deposition?

A. File?

Q. Your file information, as requested by the subpoena attached to the notice of deposition.

A. You mean billings and all that stuff?

Q. Yeah.

MR. THORNBURGH: Here you go.

A. This you should have. It's actually part of your --

Q. Not like this, though.

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MR. THOMAS: Let me mark as Jordi Exhibit Number 3 a document that you have in front of you.

(Exhibit Number 3 marked for identification)

Q. Is this your working copy of the Bellew expert report?

A. Yes. Right. Minus the data. The data is back here.

Q. Okay.

A. You have everything.

MR. THORNBURGH: Just so -- I just want to make sure that he gets the original back because it's got his notes on it. It may have his notes on it or highlighting or tabbing. So he needs to get those back, the original. We can make a copy for you, but he needs that.

MR. THOMAS: I understand that. I just need a copy of Exhibit Number 3 with his notes and sticky tabs.

MR. THORNBURGH: Sure.

Q. I have in my hand -- is this a group of documents that you recently received?

A. Yes.

MR. THOMAS: I'm going to mark collectively as Exhibit Number 4 three sets of documents. One has a cover page of November 5th, 1984. It bears the ETH MESH

Number 15958452. The second one bears the ETH MESH Number 15958336. It begins November 13th, 1984. And the last one is ETH MESH 15955462, a document dated May 2, 1984.

(Exhibit Number 4 marked for identification)

Q. When did you receive the documents that are in Exhibit 4?

A. Yesterday.

Q. And what did you do with the documents that you have in Exhibit 4?

A. I just read them.

Q. I notice there's some highlighting on those documents. Is that highlighting yours?

A. Yes.

Q. Did you make any notes based on your review of those documents?

A. No.

MR. THORNBURGH: Just so the record is clear, these are documents that we received from you very recently.

MR. THOMAS: Yeah, the record will reflect when they were produced to you.

Q. Do you have any notations, comments, written or dictated information of any kind related to the

documents you reviewed in Exhibit 4?

A. Any notes? No.

Q. Did you dictate anything electronic?

A. No.

Q. So anything that I wanted to find that's written down, memorialized, about your observations as Exhibit 4 would be in the documents themselves?

A. Correct.

Q. What other documents did you bring with you today other than what you've handed me here?

A. A copy of Shelby Thames's report, expert report.

Q. May I have that, please?

A. This would be part of that. It's his data.

MR. THORNBURGH: And again, Dave, we'll make copies so that he has the originals.

MR. THOMAS: Let me mark Shelby Thames's information as Jordi Number 5.

(Exhibit Number 5 marked for identification)

Q. What else do you have?

A. Expert report of Thomas Barbolt, expert report of Michael Greenberg, expert report of Vladimir Iakovlev, lab notebook relating to this particular case.

Q. Okay.

MR. THOMAS: I'll mark Iakovlev report as Jordi 6, the Barbolt report as Exhibit 7, the Greenberg report Exhibit 8, the lab notebook book reference, which I'll mark as Jordi Exhibit 9.

(Exhibit Numbers 6 through 9 marked for identification)

Q. This is a Jordi Laboratories lab notebook?

A. Yes.

Q. And what does Exhibit 9 represent in terms of work done by Jordi Labs?

A. Just details from the time from when the samples were divided between us and Dr. Thames, Dr. Owen, and all the various sample prep steps for various tests -- PYMS, LCMS, FTIR, et cetera -- run by Jordi.

Q. And whose handwriting -- I guess there's different handwriting on them all.

A. There's different handwritings.

Q. Whose lab notebook is this?

A. Well, it's a Jordi Lab notebook.

Q. Okay. It's not assigned any particular person?

A. No, because it's handled by -- we have a process here. And that's part of the process that we have a lab notebook for everything that's done.

Q. Is the lab notebook, Exhibit 9, dedicated to

this project?

A. Just this project.

Q. So to the extent this lab notebook starts on page 28, what's on pages 1 through 27?

A. I don't --

MR. THORNBURGH: They've been produced previously throughout the course of this litigation.

MR. THOMAS: Okay.

Q. Is there a complete copy of the lab notebook here at Jordi Labs?

A. Yes.

Q. I want to see that sometime today. Not right now.

Let's start with the Bellew case, Doctor. What did you set out to do in the Bellew case?

A. We were just asked to analyze the Bellew samples -- sample to see what we could learn about its chemical makeup, see if there were any differences between the material in it and the material in pristine.

Q. And when you say the "Bellew sample," what is the product name of the Bellew sample?

A. (No verbal response)

Q. Do you know the name of the product without looking at it?

MR. THORNBURGH: He's got his expert report.

You can refer to the expert report if you want to.

MR. THOMAS: Let's let the record reflect he's looking at the expert report to determine the name of the product.

A. We called it "pristine exemplar," is the sample, the nomenclature we use.

Q. Do you know the name of the Ethicon product that you examined?

A. Give me a second. It's in the report. TVT, TVT-O. This one was a different material.

(Pause)

Q. Doctor, that's okay. We can come back to that in a minute.

A. I can find it.

Q. You mentioned that this was a different material. What do you mean by that?

A. It was 100 microns across versus the 170-micron material that was for the TVT, TVT-O run previously.

Q. Different than -- the dimensions?

A. Different dimensions.

Q. Any chemical difference between the sample that you tested for the --

A. Excuse me. Gynecare Prolift.

Q. Okay. Gynecare Prolift is the name?

A. Gynecare Prolift TM.

Q. And you're reading from page 15 of --

A. 16.

Q. -- 16 of your report? Okay.

How was the -- Strike that.

And the materials that you analyzed previously in the Lewis case and in the Husky and Edwards case were the TVT materials?

A. Yes.

Q. How does the TVT differ chemically from the Prolift device that you analyzed in Bellew?

MR. THORNBURGH: Objection.

A. Chemically?

Q. Yes.

A. To my knowledge, it doesn't. They're both polypropylene.

Q. Did you undertake any analysis to determine whether the Prolift that you analyzed for the Bellew case is different from, chemically, the TVT that you analyzed in Lewis, Husky, and Edwards?

A. We undertook lots of chemical analyses to determine what it was, yes.

Q. Did you undertake any chemical analysis to determine whether they were -- whether the Bellew sample that you analyzed was different chemically from the TVT

samples that you analyzed in Lewis, Husky, and Edwards?

A. That wasn't the purpose of the analysis per se. We were just to analyze it.

Q. Okay.

A. We have those results.

Q. Now, all of the meshes that you've analyzed in your work in this litigation that involve Ethicon have involved Prolene mesh. Correct?

A. Yes.

Q. And Prolene mesh has as its base component polypropylene?

A. That's correct.

Q. And polypropylene mesh -- Strike that.

And the -- what makes Prolene different from generic polypropylene mesh are the additives that are included in Prolene. Correct?

A. It's their unique formulations, yes.

Q. And what is it about the -- What are the unique additives to Prolene that make it different from generic polypropylene?

A. Well, you have Santonox R. It's an antioxidant, you have dilauryl thiodipropionate as an antioxidant, and you have other additives to make it more easy to extrude the fibers.

Q. And why are these additives included with the

polypropylene to make this Prolene?

MR. THORNBURGH: Objection.

A. They're put in there to stabilize it.

Q. And do you understand that Ethicon regards the additives included in its Prolene suture to be proprietary?

A. Yes.

MR. THORNBURGH: Objection.

Q. Do you know whether --

MR. THORNBURGH: Give me a second between his question and your answer to lodge an objection. Okay? Just a hair of a second.

THE WITNESS: Yes, sir.

Q. Have you analyzed the polypropylene mesh of any other manufacturer?

A. I don't believe so. I don't run the company any more on a day-to-day basis, so it's possible somebody else has done some analysis, but I don't know of it. I don't believe we have.

Q. Do you know whether the chemical composition of Prolene is different from the chemical composition of polypropylene mesh manufactured by other companies?

MR. THORNBURGH: Objection.

A. I do not.

Q. Do you know whether the Prolene in

polypropylene sutures is the same chemical composition as the Prolene that's contained in the polypropylene mesh?

MR. THORNBURGH: Objection.

A. Repeat the question, please.

Q. Do you know whether the Prolene that is used in Ethicon's polypropylene -- Strike that.

Do you know whether the chemical composition of Ethicon's Prolene sutures is the same as the chemical composition of the Ethicon Prolene mesh?

MR. THORNBURGH: Objection. I assume you're talking about today, currently?

MR. THOMAS: Yes.

A. To my knowledge, they all contain the same additives, at least the antioxidants.

Q. Do you know how long they've contained the same additive package?

MR. THORNBURGH: Objection.

A. I believe since the time it was first introduced.

Q. Okay. When was Miss Bellew's implant?

A. I think it was taken out in 2012. Around 2008, 2009 maybe.

When she had the implant?

Q. Yes.

A. To the best of my knowledge, 2008, 2009.

Q. And when you say best of your knowledge, what is that knowledge based on?

A. Data that comes out of Steelgate.

Q. Can you give me any more firm date than 2008 or 2009?

A. I could find it easily. I don't have it off the top of my head, no.

Q. Was the date of her implant important to your opinions in this case?

A. Not at all.

Q. What was the date of her explant?

A. I understand it to be around 2012.

Q. Do you know when in 2012?

A. I do not.

Q. Is the date of her explant important to your opinions in this case?

MR. THORNBURGH: Objection.

A. Since I was trying to analyze its composition at this point in time, no, it had no bearing.

Q. Do you know how long following the explant the explanted mesh was stored in formalin?

A. Well, it would have been from the -- approximately two years. It would have been from the time of the explant to the time of our analysis.

Q. Have you sought to calculate the time that the explant for Miss Bellew was stored in formalin before you conducted your analysis?

MR. THORNBURGH: Objection.

A. I'm sorry. Have I done what?

(Record read)

A. Well, it would have to be about two years. That's all I can tell you.

Q. Did you undertake to calculate the amount of time that the mesh was stored in formalin --

A. Why would I? I'm trying to analyze -- I'm just trying to analyze, sir.

Q. I understand. I need to ask my question so I get a good answer.

A. Okay.

Q. Is it fair to understand, then, that you did not try to calculate the amount of time that Miss Bellew's mesh was stored in formalin from the time of her explant to the time that you conducted your study?

MR. THORNBURGH: Objection.

A. Well, we didn't -- to the exact day basis, no. I could say it was about two years.

Q. Okay. Do you know whether the explant was ever stored anywhere other than formalin?

A. The way it's been explained to me from Steelgate, knowing that these samples are all taken at surgery and then placed in the formalin and sent for storage.

Q. What is Steelgate?

A. A repository for maintaining samples of explanted materials like this.

Q. Did you rely on Steelgate to provide you with the history of this explant for purposes of understanding where it had been before you conducted your analysis?

MR. THORNBURGH: Objection.

A. Yeah. Yes, sir.

Q. Since your work in Lewis, Husky, and Edwards, have you identified any new literature in support of your opinions in these cases?

A. New literature?

Q. Yes.

A. Well, these new Ethicon documents. They're new to me.

Q. I'm talking about published literature. I'm sorry. Perhaps I should have been more clear.

MR. THORNBURGH: I'm sorry. Outside what's already been identified in his expert report?

MR. THOMAS: I asked about since Lewis, Husky,

and Edwards.
MR. THORNBURGH: Well, you've got an expert report.
MR. THOMAS: I'm just asking him, Dan. If he knows, he knows.
MR. THORNBURGH: If you need to refer to your expert report, feel free to refer to your expert report.
MR. THOMAS: He can answer the questions just fine, Dan. You don't have to help him.
BY MR. THOMAS:
Q. Do you know of any published literature, new, upon which you've relied since the preparation of your report in Lewis, Husky, and Edwards?
A. Well, we added new literature in the nanothermal work.
Q. Okay. Any other area that you can recall?
A. That's all in my report. That's all I can tell you.
Q. Okay. As you sit here today, can you recall any specific published literature upon which you rely in your opinions in the New Jersey litigation or the Bellew case that you did not rely on in Lewis, Husky, and Edwards?
MR. THORNBURGH: Objection.
A. Are you talking about the New Jersey case now

or this case?
Q. New Jersey and Bellew are both the subject of this deposition.
A. Okay.
Q. Those are both new reports to me.
A. Okay.
Q. I've not had the chance to ask you questions about those reports. I have asked you questions about Lewis, Husky, and Edwards.
My question to you right now is whether there's any literature of which you're aware new to the New Jersey report or to the Bellew report that's not present in Lewis, Husky, or Edwards.
MR. THORNBURGH: Objection. Asked and answered.
A. The nanothermal work -- and I should have added one more, the paper by NATTA. That's new.
Q. And NATTA, which is spelled N-A-T-T-A, which I'll mark as Exhibit 10 is titled, "Dependence of the Melting Point of Isotactic Polypropylenes on Their Molecular Weight and Degree of Stereospecificity of Different Catalytic Systems."
(Exhibit Number 10
marked for identification)
Q. Is that correct?

A. Uh-hmm.
Q. And for what purpose do you use Exhibit Number 10, the NATTA article?
A. To correlate melt point with molecular weight.
Q. Dr. Jordi, when you conducted your work in Lewis, Husky, and Edwards, you did molecular weight testing. Correct?
A. Yes.
Q. Did you do molecular weight testing in the Bellew case?
A. No. Well, we did, but we did it with nano-TA, as per the paper we just discussed.
Q. Okay. In Lewis, Husky, and Edwards, you conducted GPC testing to determine the molecular weight of the meshes you analyzed in that case. Correct?
A. Yes.
MR. THORNBURGH: Objection.
Q. Is there a reason why you didn't conduct GPC testing of the Bellew mesh explant?
A. Yes. We discovered that there's a surface layer of cracking that's degraded and the interior of the mesh is not degraded.
And so when you run GPC of the overall sample, you have this great dilution effect. Just a few micron outer layers is cracked and degraded, and then the

interior is not -- its molecular weight is not changed, so it drowns out the effect on molecular weight when you dissolve the entire sample.
To state it simply, GPC is a bulk technique. And it's not -- we discovered that it's not suitable for the analysis of what we're trying to show, which is the degradation of the surface material, which is degraded.
Q. In the Bellew report, you conclude that this outer layer of degradation is about 1 micron. Is that correct?
A. No. What that's telling us is that particular sample we looked at, there are cracks. And so when you run the nano-TA instrument across the surface, it falls in cracks and the cantilever sinks and you measure the distance.
What we said there was the depth of that particular crack we're showing in that particular location was 1 micron. But there's all different depths, depending on which crack you're in and how far you go through the surface.
So I really can't tell you exactly how thick the overall layer is from that analysis. It was primarily for -- to determine melt points, not crack dense -- thickness. But that particular one was 1 micron.

Q. How many measurements did you take of the surface layer of the degradation that you claim to have identified?
A. The surface layer? How many measurements for the melt point or the --
Q. The thickness.
A. The thickness?
Q. Yes.
A. It wasn't our goal with that assay, so we just got one and left it.
Q. Okay. And the only test that you conducted to determine the thickness of the surface layer of what you identified to be degradation was approximately 1 micron. Correct?
MR. THORNBURGH: Objection.
A. We saw one -- we measured one 1-micron crack. That's all I can tell you.
Q. Okay. Do you have any other measurements that you conducted to help you understand the thickness of what you've identified as a surface layer of degradation?
A. We weren't really going after that. We were going after chemical makeup, so as opposed to physical depth.
You could get some other estimate perhaps from

SEM, if we looked at all the SEM charts and spent some time.
Q. Fair to understand the only calculation you made of the surface layer of what you've described as degradation was the 1-micron measurement that you did by nanothermal analysis. Correct?
A. Again, our goal wasn't to do depth. Yes, we saw that 1-micron crack. That's all we saw.
Q. Okay.
A. Can I add one other thing, sir? That doesn't mean that I believe that the thickness is 1 micron. It's just that crack, that one crack was 1 micron.
MR. THOMAS: Move to strike the last comment as nonresponsive.
MR. THORNBURGH: It's okay if you need to add on to any of your questions. So if he moves to strike, don't worry about that. You can continue to answer however you feel is necessary in this deposition.
A. Sorry.
Q. In the Bellew report, you include some analysis of the work that you did in the Lewis, Husky, and Edwards case. Correct?
A. That data is included, yes.
Q. You don't include in your Bellew report the discussion of your GPC analysis. Did you know that?

A. Yes, because we don't -- we didn't do GPC in Bellew.
Q. Okay. But you do in Bellew include the discussion of the 24 TVT explants that you analyzed in Lewis, Husky, and Edwards, didn't you?
A. In which one? Which -- Yes, some like DSC, for example?
Q. No. In GPC. You did GPC work in Lewis, Husky, and Edwards. Correct?
A. Well, we said that GPC I believe doesn't -- do you want to give me a reference, sir, so I can --
Q. Sure. I will. I will do exactly that.
A. Our page numbers should match.
Q. If you'd turn to page 85 of your Bellew report, please. Are you there?
A. 85.
Q. 84 begins, "My analysis of other TVT and TVT-O controls and explants provides additional support for my opinions that Prolene degrades in vivo," and then you go through and identify the work that you did in Lewis, Husky, Edwards, and Batiste. Correct?
A. Can I see where you're at here?
Q. Same place you are.
A. Okay. First paragraph or what?
MR. THORNBURGH: I think he's just asking you

generally.
Q. This is the work that you did in connection with the TVT cases for Lewis, Husky, and Edwards?
A. Right.
Where is it talking about GPC, is I guess what I'm looking for.
Q. If you'd go to page 90.
A. I was looking for GPC and I wasn't finding it. Okay.
Q. Page 90 of the Bellew report shows the testing that you conducted on the TVT samples. Correct?
A. Yes.
Q. And about two-thirds of the way across the chart, there's a reference to GPC HT. Correct?
A. Correct.
Q. And that's molecular weight testing. Correct?
A. Correct.
MR. THORNBURGH: Objection.
Q. And where it says FM in that chart, that indicates where you conducted testing on the various samples that are on the left column. Correct?
A. Uh-hmm.
Q. Is that yes?
A. Yes.
Q. Now, I notice in your copy you blocked out the

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GPC HT column. And that's Exhibit 3. Why did you block that out?
MR. THORNBURGH: Objection.
A. Because we weren't intending to use that data because I've already explained it, because of the surface cracking was diluted by the mass of the interior material. So the GPC test didn't show anything, so we took that data out.
Q. Okay.
A. That was inadvertently left in by mistake, so that's why.
Q. Okay.
A. That heading.
Q. So it's a mistake in the Bellew report, Exhibit Number 1, for this column, GPC HT, to be in there?
A. Yes, sir.
Q. And it was your intention when you completed the Bellew report to remove reference to the GPC HT testing that you did to determine the molecular weight of the TVT?
MR. THORNBURGH: Objection.
A. Yes, because we've substituted the nano-TA.
Q. All right. Did you conduct any GPC testing on the Bellew explant?
A. No, sir.

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Q. Why not?
MR. THORNBURGH: Objection. Asked and answered.
A. Because the bulk material dilutes out the surface cracking, crack material, which is 2 or 3 percent of the total sample. So you can't see the difference anyway. It serves no purpose.
Q. Okay. Is the GPC testing that you conducted in Lewis, Husky, and Edwards valid scientifically?
MR. THORNBURGH: Objection.
A. Repeat the question, please. Sorry.
(Record read)
A. Of the bulk material, yes. Not the surface.
Q. Is there any other testing that you conducted on the Bellew explant -- Strike that.
Is there any testing that you conducted on the Bellew explant that is not included in your report?
A. No.
Q. Other than the GPC testing that we've already described, is there any testing of the TVT explants by Jordi that's not included in the Bellew report?
A. I'm not sure I follow the question.
Q. We're on page --
A. We included everything we did. I know that. This is an error. Just to make it clear, we did not do

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GPC on Bellew. So that's clear, I hope.
Q. But you did GPC for the TVTs?
A. Yes, sir.
Q. And you decided to take that out of your report. Correct?
A. Yes.
Q. Is there any other testing that you supervised in connection with the TVT devices that's not included in your report?
A. No.
Q. Have you ever conducted any tests on any Prolene explants where you found a decrease in molecular weight?
MR. THORNBURGH: Objection. I'm sorry. Can you read back the question?
(Record read)
MR. THORNBURGH: Objection. Asked and answered.
A. Yes.
Q. Which one?
A. The Bellew.
Q. The nanothermal analysis?
A. Yes.
Q. Have you ever conducted any GPC testing on Prolene explants where you found a decrease in molecular

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weight?
MR. THORNBURGH: Objection. Asked and answered.
A. No. The bulk technique shows no change.
Q. All right. Other than the nanothermal analysis, which we'll talk about in a minute, have you ever seen any tests on Prolene explants which found a decrease in molecular weight?
MR. THORNBURGH: Objection.
A. Okay. Sorry. Read it back, please.
(Record read)
A. Well, I believe the inference clearly is from Ethicon's own people, to show that it was -- that this page 248, both 19 and 18, shows that it was -- surface material was 147- to 156-degree melt, which is consistent with degraded polypropylene, which would mean by definition that it's a lower molecular weight.
Q. My question is very specific, Dr. Jordi.
MR. THORNBURGH: He answered your question very specifically.
MR. THOMAS: You know, Dan, you've said more than he has so far. Would you let me ask my questions and get my answers.
Q. Dr. Jordi, have you ever seen any specific tests for molecular weight on Prolene explants which

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found a decrease in molecular weight?
MR. THORNBURGH: Objection. Asked and answered.
A. Basically, the GPC was used by pretty much everybody for years, which ignores -- which is the bulk technique and ignores the skin degradation. So yeah, that's the major technique that's been used. And we believe now that it's inappropriate.
MR. THOMAS: Could you read my question again, please.
(Record read)
MR. THORNBURGH: Objection. Asked and answered.
A. By GPC, no.
Q. And is the only test that you've seen where you believe there's a showing of a decrease in molecular weight in a Prolene explant the nanothermal analysis that you conducted in connection with this litigation?
MR. THORNBURGH: Objection. Asked and answered.
A. And also Ethicon's own people.
Q. Okay. None of the documents that you have there that have been marked as Exhibit Number 4 identify specifically a decrease in molecular weight, do they?
MR. THORNBURGH: Objection. Asked and

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answered.
A. Well, here is a statement: "A great body of literature exists regarding oxidative degradation of polypropylene in general as well as selected studies in the photo and thermal oxidation of polypropylene monofilaments."
So an oxidation, by definition, will cause a loss in molecular weight. So that's just included in that. They understood it, all your own people. That's all I can say.
Q. Can you point to anything in the documents that you have in front of you where Ethicon found a decrease in molecular weight for explants that they analyzed?
MR. THORNBURGH: Objection. Asked and answered. He's already shown you.
A. GPC. That's all. They only -- the only test that was run at that time that I know of was GPC and/or -- they understood the effect of melt point as well. And they stated that the lowered melt point met degradation. And degradation means loss of molecular weight.
So if you're asking a technique, it's an interpretation of the data is what it is. It's not a single technique. Oxidation implies degradation, implies loss of molecular weight. They all go together.

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Q. Dr. Jordi, as a part of your work in Bellew, there was scanning electron microscopy conducted. Correct?
A. Yes, sir.
Q. And who did the scanning electron microscopy?
A. Evans Analytical.
Q. Do you have with you the file information provided to you by Evans Analytical?
MR. THORNBURGH: It's been produced to you.
A. You have it.
MR. THOMAS: In what form did I receive it?
A. These pictures. This is the file.
Q. Did you produce -- Is there any correspondence between you and Evans Analytical about the work that they did?
A. No, because we send them samples. We simply want the analysis done. They send us a report, and then we've put those charts from that report into our file, which you have.
You have some of them in here and you have the rest of them in the bulk, which you also have, the data.
MR. THORNBURGH: And, David, just so you understand, I don't know if you saw it, but within the documents we've produced this morning include the Evans Analytical work.

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MR. THOMAS: Okay.
Q. Do you consider yourself to be an expert in scanning electron microscopy?
A. I have used it for many years. I would think so.
Q. Do you know the different technologies available for scanning electron microscopy?
A. It's like all other fields, it's an evolving field. There are better detectors now, I'm sure.
Q. What are the various kinds of scanning electron microscopy that's available?
MR. THORNBURGH: Objection.
A. Well, most of it involves the amount of vacuum required and whether or not you have to sputter coat the samples. And so in today's -- the newer silicon drift detectors, and so on, you don't need to do that and you can use higher pressures. You don't have to get as high a vacuum.
Q. Do you know what backscattered scanning electron microscopy is?
MR. THORNBURGH: Objection.
A. Not off the top of my head.
Q. Who chose the kind of technology for scanning electron microscopy that was used to analyze the Bellew polypropylene?

A. Well, that was done by my son, Dr. Mark Jordi, in discussions with Evans Analytical.
Q. Did you have any involvement in determining what kind of technology to use scanning electron microscopy?
MR. THORNBURGH: Objection.
A. At the time the first analysis was done and this technology was chosen, I was on vacation. So my son, as I said, Dr. Mark Jordi, did that discussion. So I had no involvement, no, in that first one.
Q. Do you have an understanding of the kind of scanning electron microscope that was used to analyze this mesh?
MR. THORNBURGH: Objection.
A. It's all listed in the report.
Q. Okay. Without referring to your report, do you know?
MR. THORNBURGH: He can refer to the report if he wants to.
MR. THOMAS: I know that, Dan, but I can ask the question the way I did, too.
MR. THORNBURGH: Objection.
A. No, I don't.
Q. What kind of experience or expertise does Mark Jordi have with scanning electron microscopy?

A. Well, he did a ton of it in his Ph.D. program at UConn, his polymer degree program. He's done it here -- for his whole career here.
Q. Did you rely on Mark Jordi to identify the appropriate scanning electron microscopy technology for your work in this case?
MR. THORNBURGH: Objection.
A. Yes.
Q. As you sit here today, do you have any understanding why Mark Jordi chose the particular technology that he did for this work?
A. Dan Burkley had alleged that vacuum -- high vacuum drying would cause the sample to become brittle and crack and that drying was a cause of cracking. So he went to variable pressure SEM so he would use a lower vacuum and hence not cause as much drying. And that was why that was chosen, to answer that criticism.
Q. Okay. Do you know whether there are technologies available -- Strike that.
Do you know whether there are different technologies available that employ the variable pressure technique?
A. Different technologies?
Q. Yes. Different kinds of scanning electron microscopy that don't use the drying or sputter coating

that you've referred to.
A. We don't do -- they don't do sputter coating. That's an advantage.
Q. Do you know how many different technologies there are, scanning electron microscopy, to analyze these kinds of materials?
MR. THORNBURGH: Objection.
A. I don't know every technology that there's ever in place.
Q. Who conducted the SEM-EDX work?
A. Evans Analytical.
Q. And for the scanning electron microscopy, was that in California?
A. That was done in Minnesota.
Q. And the SEM-EDX work, where was that done?
A. Same.
Q. Did anybody from Jordi Labs travel to Minnesota to work with Evans Lab on the SEM or the SEM-EDX work?
A. No.
Q. Who coordinated the SEM testing with Evans Labs in Minnesota?
A. I can find that out for you. Those samples were routinely sent to Evans Analytical. We used them on an ongoing basis, just as they use us for other tests that they don't run. We have a process where the

sample -- the samples would have been sent out by Chris.
Q. Who is Chris?
A. Our sample-handling individual. I can bring her in and she can give you the . . .
Q. Was there anyone who Jordi -- at Jordi Labs who supervised Evans Labs in the scanning electron microscopy?
A. No, because it's their instrument and their expertise.
Q. Did you say "I don't know" or "no"? I'm sorry.
A. No, we didn't, because it's their instrument and their expertise.
Q. Is it fair to understand that Jordi Labs sent the samples to Evans and relied upon Evans to conduct the scanning electron microscopy it believed to be appropriate?
A. Yes.
Q. For the SEM-EDX testing, did anyone from Jordi supervise Evans in that testing?
A. I don't know what you mean by "supervising," but we requested they run SEM-EDX. We requested they run SEM after that analysis is run by their people with their expertise.
Q. Who decided what magnifications to use in the scanning electron microscopy?

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A. The operators.
Q. And those are Evans employees?
A. Evans, yes, sir.
Q. Did you specify any specific magnifications to be used in the scanning electron microscopy?
A. No.
Q. For the SEM-EDX testing, did you rely on Evans to conduct whatever tests it believed to be appropriate?
MR. THORNBURGH: Objection.
A. Given the goals to do the chemical analysis, that was our part of the direction. The actual choice of the sites and so on was Evans, the operators.
Q. Did Jordi Labs provide any direction to Evans about how to choose the sites where the testing was conducted by SEM-EDX?
A. I don't believe so.
Q. Is it fair to understand that Jordi sent the samples to Evans for SEM-EDX and relied upon Evans to take whatever steps it believed to be appropriate to conduct the tests necessary?
MR. THORNBURGH: Objection.
A. A qualified yes. There was a discussion. There always is discussions when we send samples out as to what our goals are in the analysis.
We didn't tell them what magnification to use

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or where to analyze. We said things like, "We're looking to try to see if there's a protein coat, to -- trying and see if clean areas are the same chemically as tissue-coated areas or cracks, that kind of thing."
And then the specific analysis details were left up to them.
Q. Do you have Jordi SOPs for handling scanning electron microscopy by Evans Labs?
MR. THORNBURGH: Objection.
A. That would be Evans Analytical's SOPs, not ours.
Q. Okay. Do you have a Jordi Labs SOP for the SEM-EDX conducted by Evans?
MR. THORNBURGH: Objection.
A. No.
Q. Did Jordi Labs conduct the DSC testing?
A. Jordi Labs conducted the DSC testing, yes.
Q. And who specifically conducted the DSC testing at Jordi Labs?
A. I'd have to look at the lab notebook again because there's 20-some employees.
Q. Okay. Did you have any direct involvement in the conduct of the DSC testing?
MR. THORNBURGH: Objection.
A. That is standard operating procedures. So I

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don't need to be involved with that minutiae, that level of minutiae. I simply get the data and analyze the data.
Q. Is it fair to understand that you did not have any direct involvement in the conduct of the DSC testing?
MR. THORNBURGH: Objection.
A. Well, I chose the fact that we were going to run the DSC.
Q. Is that the extent of your involvement in the actual DSC testing?
MR. THORNBURGH: Objection.
A. Yeah, I guess you'd say yes because the only thing you do is you put the sample in the pan and you run it.
Q. Who conducted the PYMS testing?
A. Another technician.
Q. Ed Jordi?
A. Right. That will all be in the lab notebooks.
Q. Did you have any direct involvement in the conduct of the PYMS testing?
MR. THORNBURGH: Objection.
A. No.
Q. Who conducted the LCMS testing?
A. That would probably be Adi, Dr. Kulkarni.

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Q. And that's here at Jordi Labs?
A. Yeah, also.
Q. Did you have any direct involvement in the LCMS testing?
MR. THORNBURGH: Objection.
A. Again, it was controlled by our SOP, our procedures, and just run. And I analyzed the data.
Q. Is it fair to understand that you didn't have any direct involvement in the LCMS testing?
MR. THORNBURGH: Objection.
A. The actual running?
Q. Yes.
A. No.
Q. It's true that you did not?
MR. THORNBURGH: Objection.
A. Yes, sir.
Q. Thank you. Who conducted the FTIR testing?
A. I think that was David York. But again, it will be in the lab notebook.
Q. So the FTIR testing that's contained in the Bellew report is conducted at Jordi Labs?
A. Yes. From the time that we did the last reports to this one, we bought our own LC -- FTIR microscope system. So we're now doing it in-house.
Q. How many FTIR spectra were taken of Bellew

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materials?
A. Well, in any case, something like this you must do an analysis and -- until you get useful -- what we call useful spectra. That's just standard operating procedure. I don't really know how many were taken.
In some cases, if you get on a bad site, you'll get a flat line. It's just -- that's not a useful spectra. That doesn't mean anything. It's just you have to -- and you have to try -- like, for example, if you take a fiber and -- I know we tried this. We tried transmission. You can't get any light through the transmission.
So if you recall in the last analysis, earlier work at Evans in California, they had to thin the fiber. Do you remember that? And so they could get light through it. Well, we couldn't get any light through it either, so we got a dark spectrum.
So we went to ATR spectrum. There's different techniques that are all accepted technologies to be used in infrared. Besides which, ATR sees the surface, which is what we were primarily interested in.
We didn't really care about the internal core, which has -- like TVC, has not been damaged as much or at all. So we wanted to look at the surface. ETR is a better technique for that.

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Q. What's the name of the equipment that you bought, your own FTIR microscope?
A. Thermo Electron FTIR microscope system.
Q. Who makes it?
A. Thermo Electron.
Q. Is there a model number or --
A. Yeah. I don't know it off the top of my head.
Q. And what are the specifications for it? What does it do that others -- can identify the quality of the equipment?
MR. THORNBURGH: Objection.
A. Well, it does microscopic FTIR. For example, the Evans unit in California could only use transmission. They didn't have ATR capability. We can do either with this system.
Q. Okay. So this is a better microscope than Evans had?
A. It's a later model, and technology always moves on.
Q. Okay. And David York is the technician that conducted these?
A. Right.
Q. And you said that -- Strike that.
What involvement did you have in the FTIR analysis of the Bellew materials?

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A. I was around on some of that because we were just discussing how we were going to run it. And I helped decide that we were going to use ATR.
MR. THORNBURGH: Listen to the question. He said in the analysis, not in the technique.
MR. THOMAS: Dan, please don't coach him.
MR. THORNBURGH: I want to make sure he understands the question.
MR. THOMAS: He's doing just fine without you.
MR. THORNBURGH: Listen to his question. I don't even know if you knew what you asked.
So I'm objecting to the question.
MR. THOMAS: I'm very aware of what I asked. Please, I have a limited amount of time here today and I'd like to get finished. Please.
BY MR. THOMAS:
Q. Dr. Jordi, what involvement did you have in the FTIR analysis?
A. It was minimal because, again, we rely on the operators to do the sample.
Q. What by "involvement" did you have in determining how to sample -- how to test the Bellew samples?
A. What did I have --
MR. THORNBURGH: Objection.

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A. -- to do with testing the samples?
Q. The protocol, how to set up and analyze the samples. You obviously had experience in Lewis where you were able to --
A. I know because, again, the Lewis was run in California.
Q. Right.
A. This was run here.
Q. And you had a problem -- Strike that.
You were not able to test the entire fiber in Lewis because of the kind of equipment they had at Evans. Correct?
MR. THORNBURGH: Objection.
A. We were. They had to work it differently. You had to thin the fiber, the undamaged fiber, to be able to get light through it to see it. They did it and we got a spectrum.
And then we looked at the flakes that were taken off in the Lewis sample. And in this case with ATR, we were able to look at the surface directly.
Q. Okay. Now, how many spectra were run?
A. I don't know.
Q. Did you produce all the spectra that you ran on the Bellew materials?
A. I don't know why on earth we were -- produced

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spectra that don't show anything. You're trying to get an analysis. So if you want the blank spectrum, they can be produced, I'm sure. They'll be in an electronic file somewhere.

Q. Do you know whether you've produced in your report all of the spectra that you generated from FTIR of the Bellew materials?

MR. THORNBURGH: Objection.

A. I would say no. I think I answered that. Because there are some spectra in the process of setting up to run that were run that weren't used.

Q. Okay. And you say those are maintained in electronic file?

A. Yeah, I could find out from David. But I think they would be. I don't know why they wouldn't be. There's nothing --

MR. THOMAS: I just ask that you preserve those. I will want to have those.

MR. THORNBURGH: As is typical protocol, send me an e-mail. We'll take your requests under consideration, as you do.

Q. Is there an SOP -- a Jordi SOP for this FTIR analysis?

A. There is for every instrument.

MR. THORNBURGH: It's been handed to you prior

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to the deposition.

MR. THOMAS: Thank you.

A. You have it.

Q. So we have a Jordi SOP for the DSC testing?

A. Yes.

Q. A Jordi SOP for the PYMS testing?

A. Yes.

Q. A Jordi SOP for the LCMS?

A. Yes.

Q. And a Jordi SOP for the FTIR?

A. Yes.

Q. Now, who conducted the nanothermal analysis?

A. That was done by Anasys.

Q. And how do you spell that?

A. A-N-A-S-Y-S. Let me check. I'm not the greatest speller on earth. I have it listed here. A-N-A-S-I-S.

Q. What is Anasys?

A. They're a nanothermal analysis company. They manufacture nanothermal coat.

Q. Have you used Anasys in the past?

A. Haven't needed to.

Q. Is this the only time you've ever used Anasys?

A. The first time we've needed it, yes.

Q. Is this the first time you have been involved

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in nanothermal analysis?

MR. THORNBURGH: Objection.

A. Yes, but thermal analysis goes back to the 1800s. This is just an updated version as technology moves on.

Q. Is there anybody at Jordi Labs that has particular expertise in nanothermal analysis?

MR. THORNBURGH: Objection.

A. If you have expertise in DSC regular TA equipment, you basically have expertise in this because it's the same data of the type that you're trying to generate thermal data. And a melt point is a melt point is a melt point.

Q. Do you know whether prior to your work in the Bellew case, whether anyone at Jordi Labs had requested nanothermal analysis for any product?

MR. THORNBURGH: Objection.

A. As I say, I don't run the day-to-day operation of the company, but I have no knowledge of anybody has.

Q. Dr. Jordi, do you know whether Evans sent you the complete file of the scanning electron microscopy images they took of the mesh in the Bellew explant?

A. That would be a question for Evans. I mean, just like FTIR, every one of these techniques tends not to -- if you're doing a professional report, you tend

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not to report data that's not appropriate.

I can give you a typical example I'm aware of here. In this particular case, we ran -- we were running PYMOS and we had a vacuum pump failure when the first analysis was run.

So there's no attempt to hide anything or anything else. But those first data weren't shipped because the vacuum pump went down, so we made fresh samples and we reran the PYMS. The rerun samples are what you have, for the simple reason that we had a pump failure in the first one.

Q. Dr. Jordi, do you know whether Evans sent you the complete SEM-EDX testing they conducted on the Bellew explants?

MR. THORNBURGH: Objection.

A. I'll give you the same answer. I don't, for the same reason.

Q. Did Evans decide which test results to send to you?

A. We told them what our goal was, to analyze the samples. And then how they chose -- after the directions were given, general directions were given, it was up to the operator who had the expertise.

Q. Okay. Same question for the DSC testing conducted by Jordi Labs. Have you produced all of the

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DSC testing conducted on the Bellew explant materials?
A. That would be in the lab notebooks you have. Because it's Jordi in-house. And DSC -- Sometimes a pan can blow and you have to rerun. But we were -- certainly we were sample limited in the explant case. We had plenty of exemplar.
I think it's highly likely every sample or every run that was made was what you have. I don't think there was anything else because very rarely you need to run extra in DSC.
Q. You mentioned a little bit ago that there was a problem in the PYMS testing with a vacuum pump that caused you to have to redo your test.
A. That's listed in your notebook.
Q. That's what I was going to ask you.
To the extent that Jordi Labs has problems with any testing, will those problems be recorded in the lab notebook?
A. Yes.
Q. To the extent that Jordi Labs conducts any test, reported or not, on the Bellew explant, should it be recorded in the lab notebook?
A. That gets a little stickier because in things like FTIR when you're trying to home in on the -- you're trying to home in on a single fiber for an infrared

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spectra, when you home in you might miss the fiber the first time. So you're not even analyzing the fiber. You're not going to report that. It just doesn't make any sense.
So that kind could of thing probably isn't reported, although the spectra might be in the electronic file.
Q. When you say isn't reported, it isn't reported in the lab notebook?
A. Well, that the sample was run would be reported. You're talking about every single spectra now.
Q. Every time a test is conducted, whether reported or not, should it be included in the lab notebook, Exhibit 9?
A. Yeah.
Q. Do you know whether Anasys conducted any tests on the materials supplied by Jordi that are not included in the report?
MR. THORNBURGH: Objection.
A. No.
Q. No, they didn't; or no, you don't know?
A. I know. There were none that were included because they only had what I sent them, what I took with me.

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Q. Did you go?
A. Yes.
Q. Where is their lab?
A. It's in Santa Barbara, right on the ocean.
Q. And why was it that you went to Anasys?
A. Because it was the first time we'd used this particular company, and I wanted to see how it was run for myself. And just like with FTIR, we want to understand what we're using.
Q. I apologize if I asked this question before. I just don't remember.
A. That's all right.
Q. Did you supervise any of the work of Anasys in the nanothermal analysis?
MR. THORNBURGH: I object.
A. I don't know how to answer that question. I was physically there. I saw everything that was done, but I'm certainly not going to go there and tell them as the expert how to run their samples once I hand the samples to them.
Q. You relied on Anasys to conduct whatever testing it believed to be appropriate to achieve the goals that you set for them?
A. And I gave them the goals and -- Yes.
Q. And you understand that Anasys gave to you all

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of the file information they had related to the nanothermal analysis of the Bellew materials?
A. Yes.
Q. What did you do to educate yourself about nanothermal analysis before you undertook this analysis?
MR. THORNBURGH: Objection.
A. Well, I've known about atomic force microscopy since high school. And this is basically atomic force microscopy run in such a way that you can measure the expansion of materials with temperature.
And I know that the -- and this is all in the report -- the instrument has a very fine needle tip on it of about 30 nanometers. And so you put the tip on a surface and then you start warming it. And what happens is as you warm the sample, the polymer, it expands. And so you get an upward slope.
And then when you reach the melt point, the material softens and the tip buries into the plastic and then so you get a turnover of the curve. And that turnover point is the melt point.
So it's basically simple. Its advantages, however, are that it can do tremendously tiny samples which we couldn't do before with our standard DSC equipment.
Q. Did you consult any specific literature about

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nanothermal analysis prior to the time that you asked Anasys to conduct these tests?
MR. THORNBURGH: Objection.
A. About a year ago I met these people at a scientific conference in Chicago, I believe, and I had discussions with them, began reading literature -- their literature at that time. And a lot of the papers are in this report. And I studied the history of the company. And I was extremely impressed with what I was seeing for general.
So when we had tiny samples at that point about a year ago, I said, "We really need to be aware of these people when we have really tiny samples. This is a technique we want to consider."
So I talked with them and we negotiated. And they agreed -- they were kind. There was another analytical lab that runs samples that we were considering as well, but we thought it's better to go right to the horse's mouth, to the manufacturer, if they would work for us. And they did. They agreed.
Q. Is it fair to understand the only literature you considered in understanding nanothermal analysis prior to the time retaining Anasys was literature that they provided to you following this conference?
MR. THORNBURGH: Objection.

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A. Well, the published data, yes. It's published data. It's not just them. It's other authors. And again, they're listed here.
Q. And you're referring to what page?
A. There's a bunch of them on page 76.
Q. Is that material that you consulted prior to the time that you engaged Anasys?
MR. THORNBURGH: Objection. Asked and answered.
A. Yeah.
Q. Okay. And who was the other lab that conducts this kind of work?
A. I don't remember.
Q. Where are they located?
A. Don't know. I can find out. Again, Adi was doing that. Dr. Kulkarni was doing the negotiations with them, so I don't know. And we may still use them in the future. It wasn't that we felt they were bad, just thought the manufacturer was the place to go.
Q. Dr. Jordi, when you began your analysis of the Bellew mesh materials, you had a exemplar that you analyzed. Correct?
A. Yes, sir.
Q. And then you had an explant that you analyzed. Correct?

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MR. THORNBURGH: Objection.
A. Right.
Q. And Exemplar A you've described as a pristine exemplar. That means --
A. Untouched, sir.
Q. -- untouched?
And Exemplar B is the untouched exemplar treated with formalin. Correct?
A. Yes.
Q. And Exemplar C is the pristine exemplar treated with a 10 to 15 percent sodium hypochlorite solution for 26 hours?
A. Yes.
Q. The reason why -- Strike that.
Is it 10 percent or is it 15 percent? Do you know?
A. Where are you referring, sir?
Q. I'll have to find the page. I got that right out of your report.
A. Are you talking about the percentage of sodium hypochlorite or something?
Q. Correct. It's on page 14 of your report.
A. 14?
Q. Yes. Do you see Portion C?
A. Oh, yeah. That's the way it comes to us from

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the manufacturer.
Q. You don't know whether the sodium hypochlorite is 10 or 15 percent?
A. The product is sold as a range. It always is.
Q. Okay. Now, the SOP document that's related there, is that the SOP that you provided to us today?
A. Yes, sir.
Q. Is that SOP new for this Bellew work?
MR. THORNBURGH: Objection.
A. I don't know if that's the first version or not.
Q. Will I be able to go to -- under -- Strike that.
Under Paragraph B on page 14 where it says "Portion B," will I be able to go to the SOP listed there and determine how you treated the pristine exemplar with formalin?
MR. THORNBURGH: Objection.
A. Yeah, I believe so.
Q. Will it tell me how much percentage formalin was used, percentage formaldehyde?
A. We used 10 percent because that's the whole process, what everybody used. But yes, it should show up in the SOP.
Q. Okay.

MR. THORNBURGH: We've been going quite some time. I need to take a bio break.

(Recess taken)

(Exhibit Number 11 marked for identification)

BY MR. THOMAS:

Q. Dr. Jordi, you were nice enough today to bring with you what I've marked as Jordi Exhibit Number 11. These are the -- I think these are the SOPs for Jordi that you produced today.

A. Okay.

Q. I've tried to put them all in one exhibit, Exhibit Number 11. I just want to understand, what is this document?

A. Well, this one was for formalin treatment of the polypropylene surgical mesh controls.

Q. Okay. And what's -- Is that a standard operating procedure?

A. Yes.

Q. Okay. And what's the purpose of a standard operating procedure?

A. To keep everything consistent from sample to sample.

Q. Okay. And is it the goal of the procedure to identify all those things in there a person is to do for

the formalin treatment for the polypropylene surgical mesh controls?

MR. THORNBURGH: Objection.

A. Yes.

Q. Thank you. If you go -- I've put several of these together in one exhibit. There's the formalin treatment for the polypropylene surgical mesh controls, sodium hypochlorite treatment for the polypropylene surgical mesh explants, separation of the tissue from the fiber for the polypropylene surgical explants, DSC analysis, LCMS analysis, FTIR microscope procedure, and PYMS analysis. I've marked those collectively as Exhibit Number 1.

As we go to page 2 of the formalin treatment for surgical mesh controls, it shows -- has a revision record. It says Revision A, date May 27, 2014, and it says "Initial release and new format."

What does that mean?

A. It would be the layout of the paperwork.

Q. Is --

A. That's designed by Mark, not me.

Q. Is --

A. Corporate.

Q. Where it says "Initial release and new format," is that the first SOP for formalin treatment for the

polypropylene surgical mesh controls?

A. No, because it says it's the first in new format. So there had to be a former one as well.

Q. Okay. In those places in Exhibit Number 11 where it talks about new formats, is it Jordi's practice to keep the old formats?

MR. THORNBURGH: Objection.

A. That would be a question for Mark. I don't know how they decide that.

Q. Do you have a recollection as to whether there is an old format of the formalin treatment for the polypropylene surgical mesh controls?

A. There should have been.

Q. Do you have a recollection of seeing one?

A. I do not.

Q. Okay.

(Exhibit Number 12 marked for identification)

Q. Let me show you what's been marked as Jordi Exhibit Number 12. This is another document that you provided to us today.

Is this the report that you received from Anasys on the nanothermal analysis?

A. Yes, this would have been the initial report from them to us.

Q. You said "initial report." Is there another report that you received from Anasys?

A. No. I just meant that this is what's incorporated in my report. You can see the same pictures and everything.

Q. Is there anything other than what's contained in Exhibit Number 12 that you received from Anasys in connection with the work that they did on the Bellew fibers?

A. I have just general company literature, but nothing that is specifically related to this. You have everything here.

Q. That relates to the work done on the Bellew explant fibers?

A. Yes, sir.

Q. Did that come to you in the mail or electronically?

A. It came to me electronically.

(Exhibit Number 13 marked for identification)

Q. Let me hand you what I've marked as Exhibit Number 13 and ask you if this is the scanning electron microscopy that you received from the Evans Analytical Group with respect to the Bellew explant?

A. This looks like the file we received from them.

Yes. It's identified as such because we worked through Scott Baumann.
Q. Okay. While you're here on Exhibit Number 13, if you go to page -- Figure 17 and Jordi 13, these are images of formalin-treated pristine implants. Correct? Explants.
A. Correct.
Q. Strike that.
Figure 17 and 18 are images of formalin treated exemplars. Correct?
A. Yes.
Q. And there is white material that shows on the fibers, kind of spiky looking material. Correct?
A. Yes, sir.
Q. What is that?
A. Well, it's buffered formalin, so it's probably buffer salts.
Q. How do you know?
A. That's the only thing in there, so it has to be. You've got your mesh in there and you've got formalin, which evaporates, and you have buffer salts so when you dry it down they crystalize.
Q. Was there any effort to test the white spiky material to see what it was?
A. No. The purpose of this test was to see if

formalin caused any damage to the fibers. And there clearly did not. So we accomplished our goal with that.
Q. As a part of your -- Strike that.
Is it proper procedure in analyzing fibers that had been treated in formalin to clean them before they're scanned?
MR. THORNBURGH: Objection.
A. I don't know what you could describe what -- it's whatever you describe that you want to do. It certainly wouldn't have been wrong to clean them. It's not wrong to do what we've done either.
Q. Is it fair to understand that these are uncleaned mesh exemplars that had been soaked in formalin?
MR. THORNBURGH: Objection.
A. The exemplars that had been soaked in formalin and dried.
Q. Okay. Without any further cleaning or preparation?
A. Without any further cleaning. And that's why you see the salt.
Q. Okay.
(Exhibit Number 14
marked for identification)
Q. Exhibit Number 14, is that your billing for the

Bellew case?
A. Yes. That's for the chemical analysis portion.
Q. Okay. Is there any other billing for the Bellew case that's not included in Exhibit Number 14?
A. Well, there will be billing for my time study, which obviously we bill periodically. So some of that is not included. My time is not included in that.
Q. Okay. There's no reference in there to time that you spent for the preparation of your report?
A. Correct. It hasn't been billed yet.
Q. And there's no time here shown for the preparation of your report in the New Jersey litigation either, is there?
A. No.
Q. Okay. Has the New Jersey litigation been billed? That report is May the 20th, 2014.
A. I'd have to check with our . . .
MR. THORNBURGH: Dave, if it has been, we'll produce it to you.
Q. And to the extent that there are time records available that show the amount of time that you've spent on this matter, I think we've requested that and I'd like to have those to ask you questions about them. Perhaps we can get them over lunch.
MR. THORNBURGH: I'm sorry. What was the

question? I think he had said that they haven't billed for it yet.
MR. THOMAS: But they have time records, Dan. I'm entitled to the records, not just the time.
MR. THORNBURGH: We'll consider your request.
MR. THOMAS: I'd sure hate to come back here and take his deposition.
MR. THORNBURGH: We'll produce it to you. I just don't know that they're . . .
MR. THOMAS: Okay.
BY MR. THOMAS:
Q. For the explant samples in the Bellew case, you had three different classifications. Correct?
A. Correct.
Q. The Explant A, you didn't disturb. You kept as it was, as you obtained it from Steelgate, and split with defendants?
A. Correct.
Q. For Explant B, is it fair to describe this explant as where the tissue was manually removed from the explant?
A. Yes.
Q. You identify in your report SOP Number 7.1.1.87.
A. Where are you, sir?

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Q. It's back on page 14, I think.
A. 14?
Q. I'm sorry. It's on page 17. I'm sorry.
A. Okay. 17.
Q. Is it fair to understand that Portion B of the Bellew explant had the tissue manually removed?
A. Yes, it is.
Q. And who did the tissue removal of Explant B?
A. Adi Kulkarni, as before. And I think he had some help from someone else, I think Kevin. That's all in the lab notebooks.
Q. It says, "This procedure was conducted using Jordi SOP Doc Number P7.1.1.89 Revision A."
How is that SOP different from the way in which the tissue was removed from the Lewis explant?
A. At the time the Lewis job was done, we didn't have an SOP because this is such a simple procedure. We decided to write one this time in response to your questions in the prior case.
Q. Okay. And is the Bellew explant the first time that this new SOP had been used for tissue removal?
MR. THORNBURGH: Objection.
A. Yes.
Q. Did the method for the tissue removal change from Lewis to Bellew?

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A. No.
Q. So rather than going back and asking the same questions I did in Lewis, it's fair to understand that Dr. Kulkarni attempted to employ the same process that he used in Lewis to remove the tissue in Bellew.
A. Yes. I was there, and I physically observed it.
Q. Okay. Did you participate at all?
A. I was there observing.
Q. What did you do with the tissue that you removed from Portion B?
A. Well, there's a picture of it in here. It was just separated and kept by itself.
Q. Do you still --
A. There was no further work done on it.
Q. Do you still have it?
A. I'd have to ask Dr. Kulkarni whether we kept that or whether it was disposed of. Everything we had was returned to Steelgate recently.
Q. What do you mean everything you had? Everything that you had that related to Bellew?
A. We had Bellew, we had all the other cases, we had -- we haven't discarded anything. So whatever discussions that Steelgate wanted, we sent back whatever we had that they wanted.

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Q. Do you know whether you sent back the tissue that you separated from Portion B to Steelgate?
A. I'll have to ask Scottie. He would know. I don't know myself. We didn't do anything further with it, so it was not of any interest to me.
Q. Okay. Portion C refers to subjecting that portion of the sample to sodium hypochlorite treatment to chemically separate the fiber from the tissue. The procedure was conducted using a Jordi SOP Doc Number P7.1.1.88 Revision A. It's referred to as Bellew, Dianne C.
Was this chemical treatment of this Bellew explant the first time that Jordi Labs had used sodium hypochlorite to attempt to separate fiber -- mesh fiber from tissue?
MR. THORNBURGH: Objection.
A. Yes.
THE WITNESS: I'm sorry.
Q. And so is it fair to understand that this Jordi SOP was written for this process?
A. Yes.
Q. What literature did you consult to draft the Jordi SOP for the separation of the tissue from the Prolene mesh fiber by sodium hypochlorite?
A. We used the method of Clave.

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Q. Did you investigate other methods?
A. Yes.
Q. What other methods did you investigate?
A. Well, we considered the Celine Mary that would -- we looked at every piece of literature that we had. We wanted to use the simplest -- as a biochemist, it's my understanding that the same hypochlorite destroys protein bonds and would be adequate, as described in Clave, so we just chose to use it.
Q. Now, up above on page 17 it says that after you separated the samples with the defendants, that you sent three of the seven pieces and returned them to counsel. Fair?
A. On counsel's direction, we did.
Q. Okay. So you had four portions of the sample available for you for analysis here at Jordi Labs?
A. Four divided half portions, yes.
Q. Okay. Now, when you received the samples, they were all in formalin?
A. Yes, sir.
Q. And you took the samples out, divided them so that plaintiff and defendants could share them?
A. Correct.
Q. And you attempted to divide the formalin in which they were stored equally as well, didn't you?

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A. That's correct.
Q. Did you ever perform any tests on the formalin in which the samples were stored?
A. We did not.
Q. Did you consider conducting any tests on the formalin in which the samples were stored?
A. No.
Q. Under Portion C, you describe a method by which you subjected an explant sample to sodium hypochlorite treatment to chemically separate the fiber from the tissue.
After the mesh fiber had been soaked in a sodium hypochlorite, there was a residue. Is that fair?
A. I'm not sure what you're driving at.
Q. Well, you had mesh fiber and then you had sodium hypochlorite solution and whatever else came off of the mesh fiber that was in the solution. Correct?
MR. THORNBURGH: Objection.
A. Not correct.
Q. Okay. Tell me where I'm wrong.
A. It's probably best shown on the picture. Bear with me a second. Page 20.
Q. That's the page I don't have. I have to come over and look over your shoulder.
A. Okay. I can make you a copy.

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This is what you're asking right here, the bottom photograph. There was nothing else. What amazed me about the sodium hypochlorite was that I expected this, having read the Clave article, it would take a little time. Within 15 minutes, the solution went dead clear just like this and the sample under optical microscopy looked dead clean.
Of course, this is the way it looked after 26 hours. But to my eye, the solution -- there was no residue, in other words. That's why I said you were wrong. It just dissolved everything except for the mesh.
Q. Dissolved everything into the hypochlorite solution?
A. Well, hypochlorite destroyed it into units that were soluble so that it looked like a clear solution. There was no residue.
Q. All right. And then did you remove the mesh fiber from the sodium hypochlorite solution?
A. Yeah. That's in the SOP. It was washed in water.
Q. Okay. Did you test the sodium hypochlorite solution after you removed the mesh fibers?
A. No.
Q. Did you consider testing the sodium

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hypochlorite solution after you removed the mesh fibers?
MR. THORNBURGH: Objection.
A. No. It had done its job. It was clean. I saw no reason to.
Q. Okay.
A. And it wasn't in any of the literature we looked at either, that kind of thing.
Q. And you determined it was clean by your visual observation and light microscopy?
MR. THORNBURGH: Objection.
A. Well, much more than that, but that's what it looked like. And it looked very clear. And then you're going to look at SEMs, which looked dead clean. You're going to look at infrared spectra, which looked dead clean, et cetera, et cetera.
Q. Okay.
A. And we looked at nano-TA, which looked dead clean, et cetera. So there were a number of other backup reasons to believe that it was clean.
Q. Looking at the SOP for the sodium hypochlorite treatment for the polypropylene surgical explants, which is P7.1.1.88 Revision A in Exhibit Number 11, and it says, "Add a desired volume of NaOCl solution to each flask."
Do you know how much sodium hypochlorite was

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added to the mesh samples for this cleaning procedure?
A. These were -- it's just a large excess. These were done, I think, in -- the procedure is described in here. I think it was done in -- it's in the SOP. I think the Erlenmeyer flasks were used.
Q. What it doesn't do is discuss how much sodium hypochlorite was used, if you want to look at it.
A. Yeah. Well, a desired volume would be enough to thoroughly cover the entire sample to a depth. So it would be -- if the sample had a millimeter, we probably had a centimeter or more.
Q. Do you recall measuring how much sodium hypochlorite was added to the Erlenmeyer flask?
A. There was such a huge excess that, no, it just would have been irrelevant.
Q. Okay. Does the SOP provide for a temperature?
A. It was at room temperature in the Clave work. So this was done at room temperature.
Q. Is the temperature specified in the SOP?
A. I don't see it, no.
Q. Okay. And how long did it stay in the sodium hypochlorite?
A. 26 hours.
Q. And how did you determine that amount of time?
A. Clave.

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Q. And you told me generally before, but why do you think that that procedure was sufficient to clean the mesh of all pertinacious materials on the mesh?

MR. THORNBURGH: Objection. Asked and answered.

A. If you want, I can show you an IR photograph before and after.

Q. In the file?

A. Yeah.

Q. We'll get to that in a minute.

A. You have huge protein bands before a treatment and you have none afterwards.

Q. Is it your opinion that the FTIR spectra, which we'll get into later, for the cleaned explant showed no proteins?

A. That's correct.

Q. Okay. Is the cleaning of the Bellew explant the only time, to your knowledge, that Jordi Labs has used sodium hypochlorite to clean tissue from mesh?

A. I believe it is because we said before in our prior work that we felt that the less treatment the better.

So we did the same thing we did in the Lewis case here. We did no treatment. That's B. And then since a lot of other people had done the sodium

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hypochlorite, we also incorporated sodium hypochlorite so we could clarify the carbonyl bands underlying the protein bands -- being covered up by the protein bands.

Q. Why didn't you use sodium hypochlorite in Lewis?

MR. THORNBURGH: Objection. Asked and answered.

A. Well, again, because I felt sodium hypochlorite is reactive and it could oxidize the polypropylene further. And I didn't want to risk damaging the protein.

I could see the carbonyl bands on the shoulders on the side of the protein bands, and I felt that was adequate. This time, we just wanted to add an additional level of analysis by adding the sodium hypochlorite. But we still continued to use all the older methodologies as well.

Q. Did you believe that subjecting the mesh to sodium hypochlorite in solution presented a risk to the mesh?

A. I did because if -- Sodium hypochlorite is a strong oxidant. If there's no antioxidants or not enough antioxidant present in the mesh, it had the potential to further oxidize the mesh, which is precisely why we didn't do it the last time. But we did

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it this time to add a level of further dimension.

And when we ran the nanothermal analysis, I was proved correct. The melt point of the sodium hypochlorite-treated mesh was lower than the melt point of the Sample B. 126.8 degrees versus I think 115, 116 degrees.

Q. Dr. Jordi, do you still -- Strike that.

Does Jordi Labs still have the formalin in which the material was provided to Jordi Labs?

MR. THORNBURGH: Objection.

A. No. The samples were returned to -- whatever we had was returned to Steelgate. The rest of it, in many cases, was completely used up because there's such a little amount.

Q. Do you still have the formalin in which you soaked the pristine exemplar?

A. No.

Q. What did you do with it?

A. It was disposed of. That wasn't part of -- Once it served its useful purpose, we were done with it.

Q. Do you still have -- Strike that.

Did you test the sodium hypochlorite in which you soaked the control?

MR. THORNBURGH: Objection.

A. No.

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Q. Do you still have the sodium hypochlorite in which you soaked the control?

A. No.

Do you want this back, sir?

Q. Sure. Thank you.

You describe in your procedure -- excuse me -- in your report a procedure where you blot the samples with Kimwipes to remove excess formalin. What does that mean?

A. Pretty much just what it says. The samples are taken out of formalin and they're blotted dry for analysis.

Q. What's a Kimwipe?

A. It's like a napkin, but it's a lab napkin that doesn't spin off lint.

Q. What is it made of?

A. I believe it's cotton.

Q. Okay. And then it says that the samples were then sectioned for OM, SEM, SEM-EDX, and FTIR microscopy analysis. Who did the sectioning?

A. That will be in the lab notebooks, but I wouldn't be -- I think that's probably Adi. Don't quote me on that until we look at the lab notebooks.

Q. Is there an SOP for sectioning the samples?

A. I don't believe so. It's just -- just used a

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simple disposable knife.
Q. Were you present when the samples were sectioned?
A. I was present when we sectioned -- when we sectioned them with Dr. Thames. I don't believe I was present when those particular sectionings were done.
Q. Did you provide any instructions to Dr. Kulkarni about how to section the samples that were used for OM, SEM, SEM-EDX, and FTIR?
A. No. He's a Ph.D. He hardly needs that.
Q. And you would expect however he did that to be detailed in the report?
A. Yes.
Q. If you go to page 13 of your report -- I'm on Paragraph 6, the conclusion reached right in the middle of the paragraph. It says, "The totality of the evidence as discussed in detail below overwhelmingly establishes that the Prolift device implanted in Miss Bellew degraded in her body, mostly caused by in vivo oxidation due to a lack of adequate antioxidants on the surface of the mesh and environmental stress cracking."
Did you limit your findings to the amount of antioxidants to the surface of the mesh?
MR. THORNBURGH: Objection.

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A. Yes.
Q. And is it fair to understand that based upon the work that you've done on this case, that the only scientific data that you have developed on the amount of degradation on the surface of the mesh is about 1 micron?
MR. THORNBURGH: Objection.
A. I didn't say that. I said the surface of the mesh. It appears to be 4 microns thick, from the work of Valadimir. And even --
Q. Who? I'm sorry.
A. Well, let's see. That's the -- Where did that file go?
Q. Up in this pile?
A. I think it's probably this guy.
Q. Dr. Iakovlev?
A. Iakovlev, yeah.
Q. I'm referring specifically now to the work that you did in this case.
A. Remember, I saw one crack, and that particular crack was 1 micron. I did not say that was the depth of the entire skin.
Q. I didn't mean to interrupt you. Have you finished?
A. That was not the depth of the entire skin.

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That was the depth of that particular crack.
Q. But that's the only crack that you measured?
A. Correct.
Q. So you have not generated any scientific data in connection with your work on this case that shows the depth of the cracks to be greater than 1 micron?
A. It wasn't my goal to determine the depth of the -- that just wasn't our goal.
Q. But is the answer to my question yes, that was the only test that you did and it was 1 micron?
A. I personally, yes.
Q. And how does 1 micron compare to the width of a piece of paper?
A. You'll have to -- I know what a human hair is, 60 microns. I don't know what a piece of paper is.
Q. Okay. Do you have any understanding at all about whether a micron is larger or smaller than the width of a piece of paper?
MR. THORNBURGH: Objection.
A. Probably smaller.
Q. And the lack of adequate antioxidants to which you refer in that paragraph refers to Santonox R and DLTDP?
A. That's correct.
Q. Anything else?

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A. No. We just looked at those two antioxidants.
Q. Okay. And you also mentioned environmental stress cracking. Tell me what evidence you have -- scientific evidence that you have in this case that proves to you that the Bellew mesh explant experienced environmental stress cracking.
A. Well, Number 1, we have the SEM work which clearly shows the cracks. So the cracks are a fact, just no way around it.
The only question left is what causes the cracks. We ruled out the protein coat from the IR work, which left us with only polypropylene.
And then we ran PYMS, which showed the presence of fatty acids and cholesterol esters, which are known even to Ethicon's own researchers to be environmental stress crack agents. They were present.
We saw oxidation from the FTIR. Oxidation will lead to cracking. Cracking will lead to the ability of the fatty acids and the cholesterol esters to get into the cracks and enlarge the cracks by environmental stress cracking. So the package just fits.
Q. Is there a way you're aware of to conduct any test to prove that, in fact, environmental stress cracking occurred in Ms. Bellew's explant?
MR. THORNBURGH: Are you asking to a reasonable

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degree of scientific certainty?
MR. THOMAS: Yes. All my questions are that way. I assume all of his opinions are that way.
A. To a reasonable degree of scientific certainty, I believe that's true, yes.
Q. I'm asking you whether there are objective tests that you can conduct to determine the extent to which Ms. Bellew's explant underwent environmental stress cracking.
MR. THORNBURGH: Objection. Asked and answered. He's already gone through those.
A. We did the -- like I said, we did the antioxidant levels. We did the IR work, all of that, and the DSC work also. Heat crystallization is also leaning in the direction of environmental stress cracking.
First of all, we have the fact of the cracking. Something has to cause the cracking. That's just 100 percent certain. It's there. So we have the combination, as I've described, of the stress cracking agents, as recognized in Ethicon's own literature, and we have the IR showing oxidation, which leads to cracks, which can be further exacerbated by the stress cracking agents and so on. So it's a package that fits perfectly.

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Q. Where did the environmental stress cracking start in the Bellew explant?
MR. THORNBURGH: Objection.
A. It had to start on the surface because that's where it is.
Q. Where on the surface?
A. Well, it's basically scattered all over it.
Q. Okay.
A. As shown by the SEM micrographs.
Q. Do you agree that fast crack propagation is a necessary part of environmental stress cracking?
A. It's part of it.
Q. And --
A. That's -- And that's -- by the way, that's when you're talking about exclusively environmental stress cracking. We're talking about a combination here of oxidation and environmental stress cracking. It's more complicated than just environmental stress cracking by itself without oxidation.
Q. You testified a moment ago that the degradation of this explant was limited to the surface of the explant. Correct?
A. Correct. First few microns.
Q. And is it fair to conclude that there had been no crack propagation through the -- Strike that.

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Is it fair to understand there had been no crack propagation past the surface into the interior of the explant?
A. Generally true, but it's not uniformly true.
Q. Did you find any evidence of crack propagation --
A. Glad you asked.
I'm sorry.
Q. Please, can I finish my question?
A. I have to get some data for you.
Q. Did you find any evidence of crack propagation in the Bellew explant past the surface?
A. Yes. No, not the Bellew. Other samples, though.
Q. Okay.
A. Would you like to see it?
Q. I just want to make sure. So all of the -- what you've described as environmental stress cracking in the Bellew explant is limited to the surface. Fair?
A. In the Bellew case, yes.
Q. Now, you said that you had some evidence of crack propagation in other samples?
A. Yes, sir.
Q. Are they samples, Ethicon Prolene mesh samples?
A. Yes.

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Q. And what samples are those?
A. I'll have to show you the chart.
Q. Okay. Is this material that you produced to us before.
A. You have it all, sir. Yup.
Q. What are you reaching at?
A. I'm reaching for the SEM control samples. It's the data, and from there it goes into the SEM.
Q. Is this part of your report in the case?
A. Yeah, it's part of the overall report. You have the written report and then you have the data files.
Q. I've got that.
A. Page 812, sir.
Q. Thank you.
(Pause)
Q. Okay. 812.
A. Figure 102. There's your crack at the bottom. It goes right through the fiber.
Q. Okay. And is it your opinion that that is environmental stress cracking, that the figure that -- SEM Figure 102 for Sample J-7959 on page 812 of your report, is it your opinion that the cracks shown in that figure are environmental stress cracking?
MR. THORNBURGH: Objection.

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A. Well, they're a crack that's propagated right through the fiber.
Q. Is it your opinion that that is environmental stress cracking?
A. Well, it has to be brittleness to happen. So under stress at the bend like that, it's likely environmental stress cracking.
Q. Is it your opinion to a reasonable degree of scientific certainty that the crack that's shown in Figure 102 on page 812 of your report is due to environmental stress cracking?
A. Yes.
Q. And is it based on anything more than just the appearance of the crack?
MR. THORNBURGH: Objection.
A. No. It's just the crack itself.
Q. Okay.
A. Okay.
Q. Is that the only example you're able to find of environmental stress cracking in your images?
A. Well, I would not say that the other cracks we see on the surface aren't partly environmental stress cracking related. But that's the only one that I saw that went clean through the whole fiber.
Q. Okay. That doesn't go all the way through the

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fiber, does it?
A. 80 percent.
Q. Okay. Did you determine what sample this was, what kind of material and from what person?
MR. THORNBURGH: Objection.
A. Yeah. Sample 1304.
Q. Is that a TVT?
A. That's a TVT.
Q. That's what I wanted to know. And this TVT was stored in formalin before you analyzed it?
A. As they all were. Yes, sir.
Q. And do you know how long the TVT that is J-7959 was implanted in the individual?
A. I'd have to go back. We can find that information out for you. I don't know off the top of my head.
Q. None of that information is contained in your report anywhere. Correct?
A. No, sir.
Q. That wasn't important to your analysis in this case?
A. That's correct.
MR. THORNBURGH: I'm sorry.
(Recess taken)
BY MR. THOMAS:

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Q. Dr. Jordi, do you agree that environmental stress cracking requires a crack initiation?
A. Of some sort, yes.
Q. What was the crack initiator in the Bellew case?
MR. THORNBURGH: Objection.
A. It's hard for me to describe that. I think the -- to some degree, it's the -- in this case, in all of these fibers, it's got to do with the double-layer structure of all of these fibers where you have a crystalline inner core and the outer more amorphous layer, which cools faster so it's more susceptible to environmental stress cracking.
Now, that allows for things like the fatty acids and cholesterol esters and whatever else to get in more easily than it would in a crystalline material. So it makes it more susceptible.
And then for initiation, you also have the oxidation clearly shown in the infrared spectra. The oxidation will embrittle a material. It's really known that as the molecular weight decreases, the material becomes more brittle.
And what we saw in the nanothermal work was 175 or so melt point for the pristine, for the formalin treated, for the -- even for the hypochlorite treated

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exemplar. But then once we went to the explants it was 126.8.
And then for the tissue extracted material, 115 or so for the general sodium hypochlorite treated. And I think it was 78 or something like that for the actual flake material. We saw flaked material on the surface of the hypochlorite-treated Bellew sample.
Q. Are you able to determine, Dr. Jordi, which came first, oxidation or environmental stress cracking?
MR. THORNBURGH: Objection.
Q. In Bellew.
A. I would think they work in tandem. I would think --
Q. Do you have an opinion to a reasonable degree of scientific certainty that they work in tandem, or are you just wondering?
MR. THORNBURGH: Objection.
A. The literature clearly states that oxidation causes embrittlement. Embrittlement is going to lead to cracking.
Q. My question is more specific.
MR. THORNBURGH: Asked and answered.
Q. Do you have an opinion to a reasonable degree of scientific certainty as to which came first with Ms. Bellew, oxidation or environmental stress cracking?

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MR. THORNBURGH: Objection. Asked and answered.
A. I can't answer the question which came first. They seem to be working in tandem.
Q. Okay. And do you have an opinion to a reasonable degree of scientific certainty the specific initiator of the environmental stress cracking?
MR. THORNBURGH: Objection.
A. Well, oxidation, as described in Ethicon's own literature and elsewhere, in Celine Mary and other places, is caused by this dual structure we talked about. And then there are crystalline regions, and then there are amorphous regions, and there are what they call tie molecules between the crystalline regions. Those tie molecules get ruptured, and that's what leads to the micro cracks. And that happens through -- one of the mechanisms is through oxidation.
So it could happen either through physical stress of the stretching of the -- When you bend the fiber mesh, the way it's constructed, you put lots of stress at the curve points, that's going to act as the stress that could cause the initial stress cracking.
Q. Doctor, you said could. Do you have a opinion to a reasonable degree of scientific certainty of what the crack initiator was in the Bellew explant for

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environmental stress cracking?
MR. THORNBURGH: Objection.
A. The initiator would be the stress. And that's a reasonable -- that's a scientifically reasonable -- to a reasonable degree of certainty.
Q. And that's stress?
A. The bending pressure. When you're bending a material.
Q. Okay. All right.
A. But the fact remains, again, it's -- we're not -- can't be debating it's cracked. It's cracked. We physically see it.
Q. And you've discussed your understanding that the outer layer of the Prolene mesh is more amorphous than the interior crystalline layer?
MR. THORNBURGH: Objection.
A. Yes.
Q. And you agree that crystallinity hinders environmental stress cracking?
A. That's a tricky question because what all the authors will say, there's a process through oxidation.
When these tie molecules break, you actually get a lowering of molecular weight, which we saw in the nano-TA by the lowering of the melt point, but you paradoxically initially get an increase in crystallinity

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and an increase in density. And then as the oxidation process continues, the crystallinity goes down and embrittlement continues to increase.
So you get an initial increase in crystallinity and then a steep drop-off. It's a process.
Q. Dr. Jordi, let's go to 165 of your report, please. The end of the paragraph begins, "Decreases in crystallinity as seen from the DSC data and the presence of cholesterol and fatty acids observed in PYMS and LCMS data are consistent with environmental stress cracking.
"Since evidence of oxidation and environmental stress cracking is seen in most samples, including Bellew, it is concluded that both of these factors may be at play for degrading the polypropylene mesh."
Is that your opinion?
MR. THORNBURGH: Objection.
A. Well, I could have said better "is factors are at play." But it's because it's more complicated than simple environmental stress cracking or simple oxidation because it's a combination of both. They're working together.
I cannot tell you and neither can any scientist in the world, I don't believe, tell you which one is more important in a particular sample because it depends on how much oxidation it's been exposed to as opposed to

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how much stress cracking agent, how much bending.
But the fact remains it's cracked. It had to be caused. So it's either caused by oxidation -- and/or. That's why I say "may."
Q. Okay.
A. But the fact that it happened is absolutely 100 percent certain.
Q. If you go to the next page, page 166, Paragraph 6 under "Summary of opinions," it says, "As a result of the manufacturing process, Prolene is susceptible to environmental stress cracking."
First of all, what is it about the manufacturing process that makes Prolene susceptible to environmental stress cracking?
A. The two-state structure of a mesh when you're finished, the outer amorphous -- more amorphous layer and the inner crystalline area.
Q. Paragraph 7 says, "Cholesterols and fatty acids absorbed into Mrs. Bellew's Prolift device, making it susceptible to environmental stress cracking, which likely contributed to the degradation and cracking in vivo as observed in the SEM images."
Again, is the -- is it your opinion that the Bellew Prolene mesh was susceptible to environmental stress cracking, or do you have an opinion to a

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reasonable degree of scientific certainty that it did, in fact, undergo environmental stress cracking?

MR. THORNBURGH: Objection. You're covering stuff we've already covered. He's already given this opinion. Asked and answered.

Hold on. I'm not going to let you ask questions over and over again and then leave and allow another lawyer to come in here and ask the same questions over and over again like you're doing here. I'm going to object. We've already covered this ground.

MR. THOMAS: Are you instructing him not to answer?

MR. THORNBURGH: You can answer the question, but we've already covered it. If we keep it up, then I'm going to start instructing him not to answer the questions.

Go ahead.

A. At this point I need to hear it repeated.

(Record read)

MR. THORNBURGH: Objection.

A. I have an opinion to a reasonable degree of scientific certainty that it was very susceptible to environmental stress cracking because of the stress, because of the manufacturing process, because of the presence of the fatty acids as described.

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Q. Okay?

A. Yes, sir.

Q. Go back to page 22 of your report, please.

A. Okay.

Q. Down at the bottom it says, "It is my opinion."

A. Uh-hmm.

Q. In the middle of the sentence it says, "this level of degradation will have a," bolded, "strong impact on fiber mechanical properties, including stiffness, elasticity, and resistance to break."

What level of degradation are you referring to there?

A. The cracking, the large level of cracking that we see on the surface. Not referring to the total fiber. We're referring to the surface material.

Q. So the surface material only --

Which you've attested in this report. Correct?

MR. THORNBURGH: Objection.

A. That's correct.

Q. -- will have a strong impact on fiber mechanical properties.

What testing have you done to determine the impact of the level of degradation that you found here on fiber mechanical properties?

MR. THORNBURGH: Objection.

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A. Well, when you look at a piece of glass, for example, laying on the ground that's been dropped and it shattered into a zillion piece, you know it's brittle. When I look at a fiber like this and see a zillion pieces, cracks, on the fiber, it's brittle. It's very obvious.

I couldn't even do mechanical testing on it because you couldn't put it into a device, if I had enough material.

Secondarily, we didn't have enough material to test on a mechanical analyzer anyway. But if we had, the melt point we saw in nano-TA of 115, 126, and 78 degrees would be so brittle because its molecular weight, according to the nanopaper, is in the 5000ish range, which is -- it's virtually not even a polypropylene anymore. It's what we call an oligomer, and it's almost turning into a powder, getting ready to turn into a powder, as evidenced by the cracks -- not just the cracks but the flake material that we see on the surface at 78C.

MR. THOMAS: Would you read my question again, please.

(Record read)

MR. THORNBURGH: Are you asking that?

MR. THOMAS: Yes.

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MR. THORNBURGH: Objection. Asked and answered.

THE WITNESS: Answer?

MR. THORNBURGH: The same way you already have.

MR. THOMAS: No. He can answer it however he needs to answer it.

MR. THORNBURGH: He's already answered the question. You just didn't like the --

MR. THOMAS: Dan, please, I'm trying to ask questions. You're talking more than he is.

A. I've lost my track. Could you read the question one more time.

(Record read)

MR. THORNBURGH: Objection. Asked and answered.

A. I would say the SEM clearly shows it's not a mechanical test per se, but it shows the mechanical effect of degradation. And the material was so brittle it cracked just sitting. It didn't need to be put on a machine. It cracked just sitting there.

Q. And you're referring to the level of degradation that you found in the report. Is that fair?

A. Correct.

Q. And when you say "strong impact," what does that mean?

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A. Well, it's not just likely to crack; it did crack.
Q. Okay. And it says "strong impact on fiber mechanical properties." Tell me -- quantify, if you can, the impact on stiffness.
MR. THORNBURGH: Objection.
A. It will make it brittle. It will just break, the least pressure put on it.
Q. The surface or the entire mesh?
A. No. The surface, sir. Everything I'm talking about is surface.
Q. Thank you. And so the level of degradation will have a strong impact on the elasticity of the surface of the mesh?
A. Yes.
Q. And can we limit it to the surface of the mesh?
A. Primarily, although I did show you the one case that we saw where it went through the whole fiber.
Q. For Mrs. Bellew's explant, can we limit the elasticity to the surface of the mesh?
MR. THORNBURGH: Objection.
A. Yes.
Q. And when you talk about the level of degradation will have a strong impact on resistance to break, what evidence do you have that there's a strong

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impact on the resistance of the Prolene mesh in Ms. Bellew to break?
MR. THORNBURGH: Objection. Asked and answered.
A. The SEM micrograph showing the break.
Q. And is that related to the surface?
A. Absolutely. Again, everything we're talking about here is surface.
Q. Next page, page 23, you say, "By potentially shedding particles of polypropylene into the surrounding tissues" --
A. Page, sir?
Q. Page 23, top of the page.
A. Got it.
Q. "By potentially shedding particles of polypropylene into the surrounding tissues."
Do you have any evidence in this case that any particles from the Bellew mesh shed into surrounding tissues?
MR. THORNBURGH: Objection.
A. Well, I didn't receive individual flakes from Steelgate. What I saw was the tremendous degree of cracking. And I did see flakes in the sodium hypochlorite treated sample of Bellew.
So it is just logical that the particles are

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going to break off with movement in the body. And the fact remains that something caused the surgery to need to be done, through the pain and stuff that required -- which I'm not a doctor, I'm not saying, but I'm just saying something had to cause that pain for the excision of the sample.
Q. You're speculating here that particles came from the mesh and caused pain and required the excision, aren't you?
MR. THORNBURGH: Objection.
Q. That's beyond your area of expertise?
MR. THORNBURGH: Objection.
A. Well, that it came off in her body, yes, because I could have analyzed flakes had I been given them, but I wasn't given them. Correct.
Q. Okay. And you don't know whether flakes from the Prolene mesh in Miss Bellew's body caused her pain. Do you?
MR. THORNBURGH: Objection. He's not going to offer opinions regarding --
A. That's not my area of expertise.
MR. THORNBURGH: -- regarding medical opinions such as the question you just asked.
MR. THOMAS: Perfect. I'm happy with that.
BY MR. THOMAS:

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Q. Is the same stipulation true with respect to polypropylene particulates caused an increased inflammatory response?
MR. THORNBURGH: Objection.
A. That's just a reference to the chemical literature that I've read that all say medical doctors everywhere, everybody says the same thing.
Q. That's beyond your area of expertise?
A. That's not my area of expertise.
Q. Thank you. For the SEM images on pages 24 to 43, is it fair to understand that Evans determined what magnification to use for those images?
A. Yes.
Q. Did Jordi give Evans any guidance or direction in determining what magnifications were to be used?
MR. THORNBURGH: Objection. Asked and answered.
A. No.
Q. Let's go to page 43 of your report, please. Page 43 begins a section in your report on SEM-EDX testing. Correct?
A. Correct.
Q. And why did you not have Evans conduct SEM testing on Bellew Explants B or C?
MR. THORNBURGH: Objection. Can you read that

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back one more time?
(Record read)
MR. THORNBURGH: Objection. I believe that mischaracterizes what he's already talked about.
Go ahead.
A. C was done because we had treated the sample -- not done because we treated the sample with sodium hypochlorite. And I would have introduced extra oxygen and extra chlorine, so I didn't want to risk the contamination issue.
We were looking for increased oxygen levels, and that would have done it. It would have misled us, so there's no reason to do it.
Q. I'm sorry. A is the as-is sample. Correct?
A. Let's go look.
Q. If you look at Table 3 on page 45, it shows the testing that you did by SEM-EDX. Correct?
A. Yes.
Q. And Table 45 shows that you did SEM-EDX testing on Exemplars A and B and you did SEM-EDX testing on only Explant A. Correct?
A. Let me file through here and see what we got.
Again, for SEM work we sent the sample with tissue only, "with mesh and tissue." That's on page 49.
Q. My question is, why didn't you have SEM-EDX

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testing done on either the manually cleaned sample or the sodium hypochlorite-cleaned sample?
MR. THORNBURGH: Objection. Asked and answered. Go ahead.
A. The manually cleaned sample would have been the same as the tissue-containing sample --
Q. Why?
A. -- for this purpose.
Because you have individual pieces of the mesh sticking out from the tissue. And those are the pieces that are analyzed here. So it would be redundant to do the cleaned material.
Q. Okay. Is it fair to understand that you could -- as far as you're concerned, you could have just as easily tested Explant B and gotten the same results as you got for testing Explant A?
MR. THORNBURGH: Objection.
A. Yes, but it would have required sending more precious sample. And they were able to use the same tissue sample they did containing tissue for this work, so why not?
Q. Is SEM-EDX destructive testing?
A. No.
Q. And they already had all three of these samples for SEM testing. Correct?

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MR. THORNBURGH: Objection.
A. Yeah.
Q. Okay. And why didn't you ask --
A. No, I don't believe for SEM, they didn't have the cleaned mesh. They had hypochlorite, they had exemplar, and then they had just the mesh.
Q. Okay. They didn't have the manually cleaned mesh?
A. Never did. Not for any of the prior work or this work.
Q. They do have the sodium hypochlorite-treated mesh?
A. That's correct. Well, they do in the SEM, but we didn't run that here because -- in the SEM-EDX because, again, we felt -- it's an oxidizing agent. It's going to put excess oxygen in the material. We're looking for excess oxygen, so it negates the purpose.
Q. Is there any benefit at all of returning an SEM-EDX test on the sodium hypochlorite-treated mesh Bellew, Dianne C?
MR. THORNBURGH: Objection.
A. Are you talking about the regular SEM now or EDX?
Q. EDX.
MR. THORNBURGH: Same objection.

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A. It would have given us an erroneous result on oxygen, so we didn't do it.
Q. Is the erroneous result in oxygen the only reason not to do that?
A. Extra chlorine.
Q. Anything else?
A. Nope.
Q. Now, to do the SEM-EDX, do you have to tell the machine what to look for, or does it just pick out things?
MR. THORNBURGH: Objection.
A. It scans, so it gives you elements right across the bottom, left to right.
Q. On Table 3 where you show the elements that are found by SEM-EDX, it shows carbon, nitrogen, oxygen, sodium, phosphorus, and sulfur.
Do you have to tell the machine to look for those elements, or does the SEM-EDX just tell you what it finds?
A. If you look at page 49, it gives you -- you see the peaks there. It gives peaks. Those are just recorded, whatever it finds.
Q. And where on page 49 it calls out the elements that it finds, are those places where the machine puts those notations, or is that something that has to be put

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on by somebody else by identifying what peaks they are?
A. The software does it.
Q. All right. And so is it fair to understand that to the extent the SEM-EDX identifies any element, it will self-identify those elements so that you can see that in your spectrum without you having to tell it what to look for?
A. Right.
Q. Okay. Other than chlorine and oxygen, what else would you have expected to see from SEM-EDX analysis of Bellew Exhibit C?
A. One of the major things we were looking for was nitrogen, if there was a protein coat. There was no nitrogen, hence no protein coat.
Q. Okay. But what else in addition to the oxygen and chlorine would you have expected to see on SEM-EDX if you analyzed Exhibit -- Explant C? Any other impurities?
A. Explant C?
Q. Yes. The clean one.
A. Explant C would have removed a protein coat so you wouldn't see nitrogen. It would increase the oxygen. It would increase the chlorine. You'd still see carbon. So those are the elements I would expect to see had we done that.

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Q. When you conducted your DSC testing, you conducted that testing on the manually cleaned sample. Correct?
A. I have to go look at the DSC results.
Q. Page 54?
A. Yes, manually cleaned, A and B.
Q. I believe you told me just a moment ago that the manually cleaned sample, Bellew explant -- Bellew, Dianne B would not be completely clean. Correct?
A. It hadn't been cleaned by sodium hypochlorite. Correct.
Q. And you agree that any impurities in the Prolene polypropylene tested by DSC will reduce the melt point. Correct?
A. Not at all necessarily. It might; it might not.
Q. Did you test to determine the extent to which impurities would reduce the melt point?
MR. THORNBURGH: Objection.
A. We did not.
Q. Okay. You didn't run DSC testing on the mesh cleaned with sodium hypochlorite. Why not?
A. I think it was primarily that we didn't have enough sample. We were very sample limited, both us and . . .

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Q. Well, that's the sample that you believe had been cleaned away from all impurities. Correct?
A. Yes.
Q. And to do a DSC analysis to determine the extent to which the melt point of the polypropylene in Prolene had been reduced, it would be better to do it on a clean piece of mesh, wouldn't it?
MR. THORNBURGH: Objection.
A. It depends on the degree that you're talking about. The amount of material shown on page 13 is minuscule. And besides which the melt point of Dianne Bellew B is 165.33 and the average -- the others is around 164. So there's no change. So it couldn't have had any effect if the melt point is the same.
Q. I don't understand the significance of your statement. Would you explain that to me, please.
A. Well, when we ran the exemplar, we got a melt point of 164. When we ran Dianne Bellew B, we got 165. They're the same within experimental error. Where is the lowering? It's not there.
If you look at the second column from the right under TM -- are you with me?
Q. Help me here. Are you saying that the melt point of Dianne B, the manually treated sample, is the same as the pristine exemplar?

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A. Yes.
So where is the imaginary contaminant?
Q. When did it degrade?
MR. THORNBURGH: Objection.
Q. I mean, I'm obviously not understanding this. I apologize for this.
A. Okay.
Q. You have a pristine exemplar out of the box and you do a DSC analysis of the pristine explant out of the box and you get a melt point of 164. You do the same DSC analysis on Bellew, Dianne B, and you get a melt point of 165.
A. Right.
Q. Which is no change?
A. No change.
Q. Okay. How does that support your suggestion that there is a decrease in melting point?
A. Well, go over to the nano-TA.
Q. Let's just --
A. We have to do this because the -- we're talking about surface here, not the total. What is DSC? It's a bulk technique measuring the entire sample.
Q. Okay.
A. But only the surface is degraded. So it's being diluted.

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Q. Now, let me -- before we go to nano-TA -- I'll let you do that, and you can talk about it all you want to.
A. Okay.
Q. Do the results in Table 5 of DSC results, as a bulk technique, is that consistent with no degradation?
MR. THORNBURGH: Objection.
A. As a bulk technique for the overall sample, it's just like the GPC analysis. Yes, it is.
Q. Okay.
A. Because the bulk sample is not degraded. The surface is.
Q. And what makes this different is your nanothermal analysis. Correct?
A. Right. There's a portion of the sample on the surface that is degraded. And if we go -- That was B. So let's -- I think it's Figure 81, page 81, AFM image of cracked region on Bellew, 121.4 degrees. That surface is degraded.
And if you then go and you look at -- Where did that go, that paper that I had from -- I'll show you how to use that paper, the nanopaper.
Can I come over?
Q. Sure. Thank you.
A. I promise to be nice.

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Q. I wouldn't expect anything else. I need to do this for the record.
So we're looking at Exhibit Number 10 and we're on page 197.
A. So here is correlation charts of molecular weight on the X axis versus melt point. And this guy is a Nobel Prize winner. He is the guy that invented polypropylene. He knows what he's talking about.
We come up here and we get into the 120s. We're at a molecular weight of about 5,000 at 120 mil.
Q. Okay.
A. Can I show you one other thing that will help explain this a little bit better?
Q. Sure.
A. I need to go on the blackboard for this one.
Q. That's fine with me.
A. If you take -- Have you got a calculator, anybody, that you can help me?
Q. Yeah.
A. You can run the numbers for me.
Say we start with 70,000 molecular weight polypropylene. And we're going to assume we have small carbonyl bands. As you know that I show my shoulder bands which are alleged to be small. And they are smallish. So I'm going to assume 1 percent degradation.

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First of all, we have to divide this number by 42, the molecular weight of polypropylene, grams per mole.
What is that number, please, 70,000 divided by 42?
MR. THORNBURGH: 1,666.
A. And then 1 percent of that is the oxidized -- I'm getting that as an estimate based on my carbonyl bands in the infrared spectrum; that's where that comes from -- would give us 16.66 oxidation points in the polypropylene.
Q. What do "oxidation points" mean?
A. Where the carbonyls are. Every --
Q. Is that a quantification? Is that a measurement?
A. Yeah, that's a measurement for the intensity of the infrared spectrum based on my 40 years -- approximately 40 years of experience.
Q. What does 16.66 oxidation points represent?
A. That's the number of points that an oxygen has been inserted into the polypropylene molecule and then leads to breaks. It degrades the molecular weight that we observe.
Q. On the surface?
A. On the surface. Not the full material.

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Everything I'm doing is surface.
So we have 16.66 break points. So we're going to divide by the number of break points. What is that number? What does that give us?
MR. THORNBURGH: 4,199.
A. 4,199. Okay. Look at your chart. What's the molecular weight predicted? If the melt rate is 120, what's the molecular weight predicted? 4,000. What have I got? 4,000.
Q. Okay. So you've used this calculation to say -- Let me back up. I'm going to keep this for a second.
A. Okay.
Q. So the traditional GPC analysis does not show the surface degradation that you've described because it's a bulk technique?
A. That's correct.
Q. The DSC analysis in your report that we've just discussed does not show the degradation of the surface of the Bellew Prolene polypropylene, again, because it's a bulk technique?
A. That is correct.
Q. What you've just described for us on the record is your calculation based upon the nanothermal analysis of the surface of the Prolene polypropylene where you've

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concluded that the surface is degraded based upon the Anasys report and this article by NATTA?
A. Yes, sir. And one more point. May I show it to you?
Q. Please.
A. As good as any is page 60, Figure 60. How did that ever happen?
Do you see how small the 1740 and 1720 bands are? Those are carbonyl bands that are the break point oxidation points I'm talking about. On that basis, I'm suggesting 1 to 2 percent oxidation.
Q. Of the surface?
A. Of the surface. Everything I'm saying is surface. Honest. I'm not trying to fool you.
Q. I just need to make it clear for the record.
A. Yes.
Q. Okay.
A. So that -- this is where my idea for the 1 percent comes from.
Q. All right. So again, the research that you've done with Anasys, the nanothermal analysis, you've identified cracks -- a crack that is 1 micron deep. Correct?
MR. THORNBURGH: Objection.
A. That one crack was 1 micron deep. Correct.

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That does not mean the whole surface was.
Q. The analysis that you just did and your reference to Figure 60 is that 1 to 2 percent of that surface area has undergone some kind of oxidation?
MR. THORNBURGH: Objection.
A. Based on Figure 60.
Q. Okay. So the blue explant -- Strike that.
Is it your opinion to a reasonable degree of scientific certainty that the Bellew explant that you analyzed has undergone 1 to 2 percent oxidation of the surface, as defined by you in this report?
A. Yes. And that's all it takes to get down to a 4200-ish molecular weight, as per the NATA paper.
Q. Let's go back to page 60.
Are the shoulders that you've just discussed that appear at 1740 and 1720 on Figure 60 on page 60 your best evidence of the presence of carbonyls that indicate oxidation on this Bellew polypropylene explant?
MR. THORNBURGH: Objection.
A. We have shown repeatedly carbonyls even when the protein wasn't removed in other charts which we also have here. But I mean, we always see carbonyls, and those carbonyls are oxidation.
Q. If you had to go point to the best evidence of oxidation of the Bellew explant, is that where you'd go?

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MR. THORNBURGH: Objection.
A. It's one point. The fact that the melt point dropped is also just as good proof of -- well, as a proof of degradation.
Q. Okay.
A. Degradation could be for mechanical things and other purposes. So yes, I mean, this shows degradation and it shows that it's oxidative degradation.
Q. Okay. I need to ask the question differently because you corrected me. And I appreciate that.
You've just gone to Figure 60. The shoulders indicated 1740 and 1720 as the evidence upon which you rely to support your opinions that the surface of the Bellew Prolene mesh has oxidized 1 to 2 percent. Correct?
MR. THORNBURGH: Objection.
A. Yes.
Q. Okay. A little bit ago we were talking about your acquisition of your new machine and the fact that you can take a number of spectra until you get the one that best represents what it is you're looking at. Fair enough?
A. Right.
Q. There's only one that I was able to find of the specific Bellew Explants B and C in your report. And

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they appear at Figures 58 and 59. Correct?
A. Well, there was only one sample. That's Dianne Bellew. So there would be one -- typically one chart for it because that was the analysis.
Q. But do I understand correctly that there may be other spectra that you shot that you choose for whatever reason not to include in your report?
MR. THORNBURGH: Objection. That's not what he testified earlier.
MR. THOMAS: He can tell me if I'm wrong. I thought he said that.
A. Repeat the question, please.
(Record read)
A. I think we discussed that before. My point is, if you look -- on page 59, for example, if you look at the fiber, you put the ATR device on top of the fiber. And if it slides off when you do the analysis, you're going to be analyzing the material behind the fiber. So that's a worthless spectrum. No, it's not included for that reason.
Q. Got it. That's all I'm asking.
A. No intent to fool anybody. When we get a good one, which this one is an excellent one here, that means we get a fiber, you get a good spectrum.
Q. Is FTIR technology such that you try to

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replicate your spectra in order to validate your findings?
A. You run a standard to show that the instrument is working properly.
Q. Okay. Did you do that in this case?
A. Every time as part of the SOP.
Q. And is the standard part of the electronic file that you maintained for this case?
A. I would imagine it is. It's standard. I'm sure it can be produced easily enough.
Q. Good. Now, if you go to page 61, Figure 61, this is where you've done an overlay of Exemplar A, which is the pristine explant; Bellew, Dianne B, which is the manually cleaned explant; and Bellew, Dianne C, which is the hypochlorite treated explant. Correct?
A. Correct. Well, one correction, sir. It's not exemplar extract. It's exemplar, because that had never been in anybody.
Q. If I misspoke, I'm sorry. This Exemplar A is a pristine exemplar that had not been --
A. -- implanted in anything. Just out of the box.
Q. What is the peak that appears at 1651, the blue peak?
A. That's protein.
Q. Those are proteins. Correct?

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A. Correct.
Q. And it's that peak that you discuss in your report that covers up the carbonyl bands that you suggest are present in the oxidized polypropylene. Correct?
MR. THORNBURGH: Objection.
A. Yeah. You can still see it. It's there at the bottom at about 1740. You can see it as a shoulder, but it's not clear. But your own people and your own report show the same sideband. It's not difficult for a trained eye to recognize it.
Q. And Exemplar A, again, is the pristine sample not implanted in anyone. Correct?
A. A, yes.
Q. And as you're looking, to the left of 1651 is the 1740 peak that you've described. Correct?
A. The blue color you're talking about? There's a shoulder. You're talking about the red?
Q. Talking about the red.
A. Yeah, that's the 1740 and 1720. You see two bends there really.
Q. Right there on that little area where it crosses the green line. Correct?
A. You're talking about this area here?
Q. I'm looking at your document now, which we've

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marked as Exhibit Number 3. And Exhibit Number 3 on page 60 you show the highlighting here. This point here is the 1740 shoulder, isn't it?
A. Yes. You can see it. Right above it is that shoulder in the blue.
Q. And the blue represents the proteins that cover up that shoulder. Correct?
A. That's right.
Q. Now, would you draw for me, please, out from the top of that shoulder and put "1740" so it's clear on your document what you're referring to.
A. Better if we have a ruler. We'll see if we can make this work.
You want 1740?
Q. Correct.
A. I hope this works.
Q. We can do it on this record, and that way -- I'm going to show you Exhibit Number 1, page 60 from that document. It's probably easier that way.
MR. THORNBURGH: I'm going to object to the extent that I'm not exactly sure what you're asking him to do. Are you asking him to just mark the 1740 or to draw a line all the way down into the spectra?
MR. THOMAS: No. I want him --
THE WITNESS: You've got steadier hands than

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me. You see that line I drew? Mark that 1740.
A. That line, you'll see that's the shoulder.
MR. THOMAS: Mark it at the end of the number so it's clear.
THE WITNESS: Do you want to write it yourself so you get it the way you want it?
MR. THORNBURGH: No, no. He's showing you the shoulder so he drew a line across through it.
A. That's all 1740, that whole line. You can put a 1740 up here or there. Either way, it's fine. That way it doesn't interfere with viewing.
Q. As you go to the right of this 1651 peak, there's another peak in the cleaned explant in red that's not present in the Exemplar A. What is that?
A. I don't know exactly what it is, but it's from the oxidized sample. It's definitely not amide II because the frequency doesn't match.
Q. Okay.
A. Again, if you drop another perpendicular from that peak, it's dead in the valley, so it's hidden.
Q. Would you do me a favor? You can't pick that up. Would you extend that line?
A. Where do you want it, sir?
Q. Extend the line up here.
A. You want it up?

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Q. Up. Great. And put a question mark there because you don't know what that is. Or I'll do it if you want me to.
A. Yeah. My old hands are --
Q. That's all right. I'm going to do it right here. Fair enough? Did I put it in the right place?
A. Yeah.
Q. Just so the record is clear, to the right of the 1651 peak that we identified in the other chart, there's a peak in the oxidized -- what you say to be the -- Strike that.
Just so the record is clear, to the right of the 1651 peak there is a peak in the sodium hypochlorite-treated explant sample of Ms. Bellew that you don't know what that is?
A. I just know it isn't amide I and amide II. My main concern was, was it protein? Did we get the protein off? And it doesn't fit either amide I or amide II so hence it can't be protein.
Q. Is there any methodology that you know available to you to help you identify what that peak is, the peak marked by the question mark on page 61?
A. Well, we did spend -- we could spend a lot more analysis time on it, and money if desired. We could go after and run PYMS on the -- we've already done that,

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perhaps.
I'd have to go back and look and see if we can pick up structural molecules that might have some absorbances in that region from the mass spectra that we have.
It wasn't an area of concentration because they're concentrating on additives and fatty additives and cholesterol esters and other stuff. It's not a protein and it's not oxidation, so it had minimal interest.
Q. Okay. But it's not consistent with pristine polypropylene. Correct?
A. No. It's something that's happened to the mesh in the oxidation process.
Q. Okay. Now, when you do LCMS testing, do you identify for the machine the substance that you're looking for?
A. Well, you run standards. You also have massive missed tables of standards that the machine matches up and gives you estimates for. If you find a hit, then you want to quantitate it and then you run a standard and you extract an ion.
So you're only seeing, like, dilauryl thiodipropionate. So you're only seeing the thing of interest. So you home in on materials like this that

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way. We have to do similar kinds of analysis here.
The other thing is PYMS C's hydrocarbon is better. And any material to show up in LCMS has to be ionizable, and not all hydrocarbons are. So you typically do not see hydrocarbons in LCMS, so you use both techniques to get the overlap and get a complete picture.
Q. Okay. I better ask the question this way, and it's because I don't understand. And I apologize.
When you conduct LCMS testing on a polypropylene mesh explant, do you have to tell the machine what to look for or will it just automatically tell you what it finds?
MR. THORNBURGH: Objection.
A. It will give you a hit list, and then you have to look for the hits that make sense.
Now, in your case, we know you put in dilauryl thiodipropionate so we look for it.
Q. I see.
A. And then we run a standard to prove it, sir.
Q. And so you have a list of chemicals that you're looking for, and you try to match that up with the LCMS data?
A. And you also use -- if it's a total unknown -- if I didn't know what you'd done and I came in with --

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you just gave me a mesh and didn't tell me that you had these additives in there, then I would run it. I would still be able to identify from the NIST hits.
Q. For the question mark on page 60, that we don't know what showed up on the FTIR analysis, would that show up on LCMS?
A. Maybe, maybe not. What is it? Is it a hydrocarbon? Is it oxidizable? Ionizable? I don't know. I don't know how to answer the question.
I wouldn't see that band directly because that's a Band 1. Infrared sees functional groups. This is CH. This is OH or NH or both. This is C double bond O. This is methylene. This is methyl bend and so on.
Infrared shows you functional groups in a single molecule. It doesn't show you the molecule.
Q. Okay. Would the peak which appears on your FTIR spectrum in Figure 61 which you've marked with a question mark show up in PYMS data?
MR. THORNBURGH: Objection.
A. Would the peak show up?
Q. The identity of the chemical.
MR. THORNBURGH: Objection.
A. Those are only functional groups, so I don't know. It would be a research project to find it, is what I'm trying to describe to you. It's not simple.

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Q. Okay. Go ahead. I don't want to interrupt you.
A. When we're looking at your sample, we're seeing amide I, amide II. We know that's got a protein. If those go away, we know we don't have protein.
I also know that this is polypropylene. I can identify from a spectrum. I've identified by IR from the total spectrum. In other words, it's a fingerprint.
In other words, polypropylene looks like this. That's polypropylene, the green. All these little bands, those are the fingerprint bands. You got the fingerprint bands, these amide I and amide II and NH for protein bands.
Q. Let me ask the question this way. Are you finished?
A. I think so, sir. I'm trying to do my best. It's complex.
Q. Okay. Let's say I know what that is. When I say "that," I'm referring to the peak that's referred to on Figure 61 on page 61 marked with a question mark. If I know what that is and I know where to look in the LCMS data, can I find it?
MR. THORNBURGH: Objection.
A. Again, I don't know how to answer that. It's not a simple yes or no because if it's a hydrocarbon, I

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will miss it in LCMS.
Q. Okay. If I know the name of this chemical that we've marked on Figure 61 with a question mark because we don't know what it is and I looked at the PYMS data, would I be able to find it?
A. If it's a hydrocarbon, you would see it.
Q. Are LCMS -- is LCMS not sensitive to nonhydrocarbons?
A. It's true, because it's not -- they aren't ionizable.
Q. Is PYMS sensitive to anything other than hydrocarbons?
A. There's a certain amount of crossover between the two techniques, but they're complementary techniques. And for a complete picture you need both, a chemical composition.
Q. If you use both and you know the name of the substance that appears on Figure 61, do you think we'd be able to identify it?
MR. THORNBURGH: Objection.
A. I think so.
Q. Is there a 1710 peak in your Bellew C?
A. There is a bunch of carbonyls that are grouped here from about here. So this valley starts --
Q. Let me back you up to the one that's marked by

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the machine. That might help you better.
You look at your Figure 60 which shows your FTIR spectrum for Bellew, Dianne C, there's no 1710 peak noted there, is there?
A. There isn't. But you'll notice that this line is coming down to the center of this total -- totality. My personal belief is that there's three things in here. The 1720 is in the middle, the 1710 is here on the side.
Q. Okay.
A. But the machine didn't catch it because it's not an individual peak like this.
Q. All right. And is there any significance to the fact that the 1720 and the 1710 peaks are below that of the exemplar?
A. They're not really below. It's just that the baseline set on the machine makes it look that way. But they're not lower than the -- I mean, we could easily have raised the red line up or lowered the green lines. What you'd need -- here is the -- you push these both down onto the red, then the red will be above it.
What you're looking for is the differences from the flat. In other words, that's the flat of this one. So I'm looking for an increase above that flat or an increase above this flat.
Q. Okay.

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A. That matters.
Q. In your New Jersey report, you identify two meshes that you analyzed where you did not observe any cracking. Do you recall that?
A. I recall that, yes, sir.
Q. Did you do FTIR analysis on the two meshes where you did not observe any cracking?
MR. THORNBURGH: Objection.
Q. It is at the back of the report.
A. I'm looking. This is the back. The New Jersey -- I got to go -- let's look in here first. I don't think I show it here.
Which one am I looking for, Dave?
Q. I don't have a cite for you to the page number. I was just asking --
A. Go to page 143 and you'll be right there.
Q. Do you recall whether you did FTIR analysis of the explants for which you found no cracking?
A. Let's see. Can you give me the ID of one of the samples? They would be in the -- I might have it here.
Q. Samples 13,419 and 13,421 showed no visible signs of cracking, per page 92 of your Bellew expert report.
A. There's a bunch more that were run that aren't

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recorded in the -- that's 13,419, 13,400, 13,405, 13,412. It doesn't appear that I have spectra of those.
Q. Do you know whether spectra were taken of samples 13,419 and 13,421 and not included in your report?
A. It's possible, but I doubt it. I can check.
Q. Okay.
A. Since they didn't show cracking, they gave no evidence of oxidation, which we readily admitted in the report.
Q. I understand. And that's what I wanted to understand is once you concluded that 13,419 and 13,421 did not show cracking under scanning electron microscopy, you concluded that there was no need to test further?
A. Correct. And we made no allusions to them being damaged in the report. Just the fact -- we made it just the opposite, that they weren't damaged.
Q. Do you still have those samples?
A. No, sir. They've been sent back to Steelgate.
MR. THORNBURGH: As you know, David, we've offered those to the defendants for now over a year.
THE WITNESS: They're at Steelgate. They can still obtain them if they want.
MR. THORNBURGH: They know they can. I've

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offered for the seventh or tenth time now.
Lunch is here, if it's a good time to break.
MR. THOMAS: Yup.
(Lunch recess)

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AFTERNOON SESSION
BY MR. THOMAS:
Q. We're going back to Exhibit Number 10, Doctor, your explanation of the nanothermal analysis and molecular weight issues.
When you look at what you have suggested is decreased molecular weight in the Bellew explant because of the nanothermal analysis, are you talking about number of molecular weight or molecular weight?
MR. THORNBURGH: Objection.
A. Well, there's three definitions, as you know. There's MN, MW, and MZ. We're talking about MN, which is number average.
Q. And why is number average important as opposed to the others?
A. Well, it's just that that's the most apropos typically with -- Polymers always have mixes of molecular weight. So we really, in broad spectra polymers, we need to consider the breadth of the molecular weight distribution if we're analyzing the polymer. All three of those numbers have their uses.
Q. But in terms of understanding the decreased molecular weight insofar as it relates to Ms. Bellew and your nanothermal analysis, you're looking at it from the perspective of molecular number?

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A. Correct.
Q. Let me jump to the New Jersey report quickly.
As I understand it, you have not analyzed any explants from the New Jersey consolidated litigation. Correct?
A. No. That was consolidated, so that was all prior work.
Q. But there are six plaintiffs in that litigation specifically named. Do you know the names of those plaintiffs?
A. No.
Q. So is it fair to understand -- Do you know whether you've examined any specific explants for any of the named plaintiffs in the New Jersey litigation?
MR. THORNBURGH: David, it was our understanding that that position would only be related to the Corbett New Jersey plaintiff and the Bellew plaintiff. It was not our understanding that you'd be asking questions about other New Jersey plaintiffs.
MR. THOMAS: Well, here is -- I guess --
MR. THORNBURGH: I don't know that it matters, but my understanding is you'd be here to depose him on Corbett only.
MR. THOMAS: Okay. Which means that I'll be back here.

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MR. THORNBURGH: Okay. I'd rather handle it all now if we can.
MR. THOMAS: I'll do it your way. It suits me just fine. What's Corbett's first name? It's okay.
BY MR. THOMAS:
Q. Have you analyzed a mesh explant for Mrs. Corbett?
A. I need to see that report.
MR. THORNBURGH: Here is your report.
A. We're off of this other one, Bellew?
Q. We'll be back to it. I just want to do something before I forget. I don't think you have. If you have, it will be a longer day than I thought.
MR. THORNBURGH: He is asking if you received an expert for the Corbett case to analyze.
Q. If you did -- We haven't. I don't think you have.
A. I don't have any recollection of it. That's what I'm trying to say.
Q. Okay. Do you have an opinion to a reasonable degree of scientific certainty that the TVT mesh implanted in the plaintiff Corbett degraded?
A. If I didn't analyze the sample, I can't speak to that. I have no chemical analysis for that.
Q. Okay. And is it fair to understand as well

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that you don't have an opinion to a reasonable degree of scientific certainty that the mesh explant for Mrs. Corbett oxidized?
MR. THORNBURGH: Objection.
A. Same answer.
Q. And is it fair to understand that because you have not looked at the mesh explant for Mrs. Corbett, you can't have a degree -- have an opinion to a reasonable degree of scientific certainty that the Corbett TVT mesh underwent environmental stress cracking?
MR. THORNBURGH: Objection.
A. Same answer.
Q. And is it fair to understand that you require an opportunity to analyze a specific mesh explant before you're able to give the opinion that that mesh degraded, as you've described it in your New Jersey report and your Bellew report?
MR. THORNBURGH: Objection.
A. In general, as you see in this Table 2 where it lists all these other samples, 24 samples I think that were run, after you see enough of these being the same, you begin to -- you see a pattern.
So I would have an opinion it's likely. But can I say specifically to that one? No, I can't,

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because there were two exceptions that weren't cracked.
Q. And before you're able to offer an opinion that any specific mesh explant degraded, as you've described it in your Bellew report and your New Jersey consolidated report, you would want to analyze that explant --
MR. THORNBURGH: Objection.
Q. -- correct?
A. Yes, if I had to have definite personal opinions --
Q. Okay.
A. -- of a specific sample.
Q. Different scientific opinions?
A. Opinions of a specific sample.
MR. THORNBURGH: Objection.
Q. Let's go back to Bellew. And we're going to go to the PYMS section, page 62.
A. 62?
Q. Correct.
A. I'm with you.
Q. All right. You state here your opinion that antioxidants leach away from the surface of the polypropylene fiber. Is it fair to understand that your opinion in this regard is limited to the surface?
MR. THORNBURGH: Objection.

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A. Yes.
Q. Do you have any evidence that antioxidants leach from the Prolene polypropylene fiber deeper than the 1 microns of measurement that you've made with your nanothermal analysis?
MR. THORNBURGH: Objection.
A. The other work -- I can't pronounce the name. Iakovlev, the depth appears to be closer to 4 to 5 microns from Iakovlev's -- I don't know how to pronounce that.
Q. That's why we're not on video.
Is it fair to understand that the work that you've done limits that to 1 micron?
MR. THORNBURGH: Objection.
A. No, not at all. The one crack that I did see was 1 micron. And that's all it says. There were other cracks. We did not measure them.
Q. And the range that you identified from Dr. Iakovlev's report is up to 4 to 5 microns?
A. That's what I saw in his report.
Q. All right. Are you able to tell us how long it takes for antioxidants to leach from the Prolene polypropylene? At what rate?
MR. THORNBURGH: Objection.
A. Well, Clave, for example, stated in his 100

explants that I think the first three months nothing showed up. And then you get progressive damage showing up with length of time of the implantation. So it seems to be a progressive thing.

The exact rate can vary all over the map, depending on how I treat it. If I put it in chloroform or THF, it will extract at a much higher rate than in the body certainly. I can get it to extract overnight easily from the surface at least in those solvents.

And I think if I dissolve the whole fiber, I can get the whole thing. I can get it all out. But in the body, I have to rely on medical studies and not my work.

Q. Is it fair to understand that you've done no studies to determine the rate at which any antioxidants leach from Prolene polypropylene in vivo?

A. Time studies, no. We've relied on other papers.

Q. Other than Clave, can you point to any literature to provide you with information about the rate at which any antioxidants leach away from the surface of Prolene polypropylene?

A. I think Barbolt and others and your own researchers clearly state that it leaches out over a period of time. The dog study ran -- I don't know -- it

was called a 10-year dog study, but it didn't run that long. It ran six and a half, seven years. I forget. But the damage increased with the time of implantation.

So it seems to be a year or two needed for damage to become -- no damage seems to be seen before three months. That's all I can say.

Q. Okay. Have you seen any literature that suggests that any oxidation of the surface area of the polypropylene mesh stops after a period of time?

A. I have not seen that, no.

Q. Okay. And you acknowledge that formalin has some effect on extracting at least Santonox R from the mesh?

A. Santonox R is partially extracted by formalin. That's true. 10 percent formalin.

Q. How chemically does that happen?

MR. THORNBURGH: I object.

A. Well, it's acting as a solvent. And it's -- I don't know that it -- "happening chemically" is the right way to phrase it. It's just extracting.

Any organic solvent will have -- Number 1, it has to be able to dissolve the polymer or the additive of interest. And then it has to be able to swell the polymer that you're trying to extract it out of so that it can get -- the solvent can get into the swollen

polymer and remove the additive.

So it's got to do with the ability of, in this case, formalin to solubilize the additive and secondarily to swell the polymer. Because even if it solubilizes the additive, it doesn't swell the polymer, it won't remove the additive.

Q. Did you study the extent to which formalin undergoes any chemical reactions with the additives in Prolene polypropylene?

A. We did not. But dilauryl thiodipropionate is an ester. It has no reactive function group to react with it, so it would be inert.

Q. DLTDP is inert?

A. Well, it's an ester. It has no active functional group to react with a formaldehyde.

Q. Okay. Is it your opinion that none of the additives in Prolene polypropylene react chemically with formalin?

A. Well, Santonox R under the right conditions might react because it does have reactive functional groups, the hydroxy groups and the molecule.

Under the right pH conditions, and so on, it could be reactive or not reactive, depending on whether it's -- it would require acid or based catalysis in order to be reactive. And your material at the formalin

is buffered, so it's at a neutral pH, so it should not react.

Q. Is it fair to understand that when you did your PYMS analysis you did not look for any chemical substances that would be formed by reactions between formalin and any of the other additives to polypropylene to make Prolene?

MR. THORNBURGH: Objection.

A. Well, had it occurred, I believe we would have seen it and mentioned it. But we didn't see anything. Again, the dilauryl thiodipropionate has got no reactive functional groups, and the Santonox R is at a neutral pH which should not be reactive either.

Q. Did you look at the issue of whether DLTDP is inert as a part of this analysis?

A. Inert?

Q. I guess that's the word you use.

A. Well, it's an antioxidant. I'm talking about for chemical reaction with an aldehyde. I'm not talking about being inert under all conditions.

Q. I'm sorry. I misunderstood you.

Did you analyze the extent to which DLTDP is inert with respect to formalin?

MR. THORNBURGH: Objection. Asked and answered.

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A. No. It doesn't have any reactional functional groups to react.
Q. Okay. In your report you refer to molecules that you identified in your PYMS testing. And on page 66, you say in the middle of the page beginning with, "Cholesterol, cholesterol-like molecules, and fatty acids, such as palmitic acid," et cetera, "were also observed in the PYMS chromatograms of the Bellew sample."
And it was important to you that they were detected below the surface. Why is that important to you?
A. Because it really wouldn't -- because the way the samples were made and they've been implanted for years, there would not be expected to be any large amount on the surface. The only place you're going to get it is from below the surface.
Q. Okay. And you identify the eight molecules that you found on Table 9 as a result of your LCMS results. Correct? That's on page 69.
A. Yes. It's LCMS, not PYMS.
Q. I understand. And it's -- Is it ricinoleic acid?
A. Ricinoleic acid.
Q. Arachidonic acid?

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A. Arachidonic.
Q. Oleic acid?
A. Oleic acid.
Q. Diglyceride?
A. Yes.
Q. Cholesterol linoleate?
A. Yes.
Q. And glycerol palmitate dilinoleate?
A. Right.
Q. All of those are present in the Bellew explant. Correct?
A. They were identified by the mass spec, yes.
Q. Did you measure how much of these materials were in the Bellew explant?
A. It wasn't our purpose to quantitate those. It was to look to see if they were present.
Q. So you --
A. They were quantitating the additives, your additive, not these compounds.
Q. So is it fair to understand that you did not undertake to identify how much of these eight substances were in the Bellew explant?
A. Each one of those would have required a separate calibration curve, so it would have been a huge amount of work. Could have been done. We didn't choose

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to do it.
Q. Okay. How many of these eight substances have carbonyl groups?
A. They all do.
Q. How can you distinguish by FTIR these eight substances on Table 9, page 69, from what you call oxidized polypropylene?
A. In Chart 61?
Q. Yes.
A. Easy. The sodium hypochlorite would destroy these molecules along with -- it just cleans the surface. There's nothing there but polypropylene.
Q. Okay. Did you test Bellew Explant C to determine the presence of these eight substances? That's the clean one. Strike that. Hang on a minute.
Look at the top of Table 9. It says, "Compounds unique to Bellew, Dianne B and C."
This suggests, as I read it, that these eight substances are in the sodium hypochlorite sample. Is that true?
A. I would say so, yeah.
Q. So the question again, if these eight substances are in Bellew Explant C, the one cleaned with sodium hypochlorite, these eight substances each have carbonyl groups, how can you distinguish the presence of

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these eight substances in the FTIR analysis on -- in your FTIR section of your report?
A. LCMS can see parts per billion. You can see levels of parts per million easily. It's just that it's there, but it's there at very low levels, so it would not be at levels -- you can't even see something in the infrared until it's at roughly 1, 2 percent. So it's an order of magnitude issue.
Q. You just told me a minute ago that you didn't undertake to quantitate how much was present.
A. Yeah, but we know from the peak size in general that -- what the response factors are. So it's -- these are not huge amounts. These are -- they're detectable amounts by this technique.
Q. Okay.
A. The same is true for PYMS.
Q. Tell me the scientific basis for your opinion that the carbonyl group peaks generated by these eight substances in Table 9 on page 69 are not what you see in your FTIR analysis.
A. There are two lower levels to see by IR, even though they are detectable by LCMS.
Q. And that's because of your conclusion that the amounts are so small that they wouldn't show up on FTIR?
A. Right. Typically you don't see anything less

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than 1 percent minimum for strong groups of carbonyl in infrared, whereas we can see part per million easily, sometimes part per billion levels, in the LCMS.

Most of these peaks that you look at in all of these charts are smallish. They're low levels. The biggest -- To give you one example, look at page 72, the bottom figure, 71. This is Exemplar A, untreated, this particular one.

There's your dilauryl thiodipropionate. The peak is off-scale. That's only .4 to .6 percent because it's pristine, brand new. That's with no time for extraction.

The levels that would be found in -- Let me see if I can -- in the extracted sample -- I mean the explant samples. Let me see if I can find those.

MR. THORNBURGH: Page 74.

A. 74. Okay. That's the one for the Santonox R, I believe. Yeah.

So the green one is Bellew, Dianne B, without tissue. The black one is Dianne Bellew with sodium hypochlorite-treated. You see how much lower those levels are than -- What I'd like to see is the dilauryl thiodipropionate one. Let me see if I can find -- It must be up in the front.

MR. THORNBURGH: Page 10. Sorry. Page 72.

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A. That's a good one. So green is Bellew. This is for dilauryl thiodipropionate. Top chart, page 70. We have Exemplar A, untreated, and then we have -- that's the biggest peak. And then we have formalin treated and we have hypochlorite treated.

These are -- Basically, they're just showing that to get any -- these responses, you've got .4 percent. In the case of Exemplar B and C, they've been sitting in the body for a while, about two years in her case, and so the levels are much lower since the peaks are smaller.

So that would translate to the percentages apparently of the explanted samples being -- I think the calculation we got -- it's in the report. We've got something like .04 percent left after two years on the explanted material, which would be .04 percent of .4 percent put in originally, which would be completely undetectable by infrared.

Q. Okay.

A. And the other molecules would be on that order of magnitude or less. You can't really even see -- most of these I think were seen -- some of them were seen in LCMS and some were seen in PYMS.

Q. Would you look at page 403 of your report, please.

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A. 403?

Q. It's back in your data section.

(Pause)

Q. Are you there?

A. I believe so, at 403.

Q. At the bottom there, there's -- first of all, what are these?

A. They're mass spectra.

Q. And what does a mass spectra do?

A. Mass spectra.

Q. What is a mass spectra?

A. I'm just trying to help her spell.

It's a fingerprint, just like an infrared. When a molecule fragments in a mass spec, it gives a series of ions. And each of those straight lines up are one of the ions. The number above it is the molecular weight of the particular ion.

And when all of those ions are put together at the specific intensity levels that are seen, then they match a particular compound. It is a fingerprint.

Q. And the fingerprint that allows you to identify hopefully specific compounds that may be present in what you've analyzed?

A. That's the goal. Yes, sir.

Q. If you look at the bottom of 403, is that a

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compound that results from a reaction between DLTDP and formalin?

A. No.

Q. Why not?

A. Because it's the same structure as dilauryl thiodipropionate except -- Go ahead.

Q. Is -- What I'm looking at is the bottom of page 403. Are you saying what we're looking at there is DLTDP?

A. It's an analogue. When you buy dilauryl thiodipropionate, you really get a mixture of chain links, 10, 12. This is didodecyl, so this is C12. I think -- lauryl I think is C12, so this would be DLTDP.

Q. Okay.

A. But they have other -- When you buy a commercial DLTDP, if you analyze it you'll find different chain links.

Q. When you analyzed the Prolene polypropylene mesh for the presence of DLTDP, did you include in that analysis all of the different variations of DLTDP?

A. The majority is found in one peak, by far. So it's just irrelevant. It would be way less than 1 percent error.

Q. How do you know that?

A. Because you'd see them in the peaks. Because

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they would ionize just like the dilauryl thiodipropionate, have a series of peaks, bing, bing, bing.
Q. Okay.
A. And even if they don't separate on the chromatogram, that means they would be under the same peak and they would be integrated in the same area and would fall under the same calibration.
Q. Do you know how many of the analogues of DLTDP are not picked up by your methodology to detect DLTDP?
MR. THORNBURGH: Objection.
A. Dilauryl thiodipropionate responds beautifully. In all the analogues it responded beautifully, too. They all ionize similarly.
Q. I thought you told me a minute ago that your methodology did not capture all of the DLTDP analogues, but you said the majority of them.
MR. THORNBURGH: Objection. That's not what he said to you.
A. It would see them all because they would just be varying chain links. They would show up in the same types of peaks that I showed you.
Here is a good way to look at this.
Q. Is the analogue that you've described on the bottom of page 403 a derivative of DLTDP?

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A. No. It's the same. It's C12.
Q. Okay. Let's go to 363.
A. 363. Got it.
Q. 363 in Exhibit Number 1 at the bottom, what is that compound?
A. It's identified isooctyl 3-mercaptopropionate.
Q. Are you familiar with that compound?
A. It's just identified by the computer. It looks like a hydrolysis product of something similar to the dilauryl thio compound, but it's because it's got sulfur in there.
Q. Are you able to determine whether the material identified at the bottom of page 363 is the result of a chemical reaction between formalin and DLTDP?
MR. THORNBURGH: Objection.
A. Let's see. What's the retention time? 7.193 minutes. So now you've jumped from LCMS to PYMS, I believe.
Q. Probably have. I'm sorry.
A. So now I got to go back to PYMS.
Q. I didn't do that with an intent to deceive. I did that because somebody gave me a note. There's a difference.
A. There is, huh? As long as you don't do it, it doesn't matter?

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MR. THORNBURGH: You didn't intend to deceive. The person that wrote the note -- I'm just playing.
BY MR. THOMAS:
Q. Do you see that's highlighted in your copy?
A. What's highlighted, sir?
Q. Are you looking at the --
A. I'm at PYMS now. So it's fair, this is the PYMS -- I'm looking at the retention time here, which is 7 minutes. So I'm going to look at 7 minutes. 7.193 minutes. So we're right here.
Q. "We're right here" meaning what?
A. Well, that's around 7.1 minutes.
Q. You're on page 64?
A. Yeah.
Q. And what does that tell you?
A. Well, it tells me that this peak out here at 12.8 minutes is dilauryl thiodipropionate.
Q. Okay.
A. The other one wasn't identified because it isn't dilauryl thiodipropionate. We're trying to quantify dilauryl thiodipropionate.
Q. My question is, is the material on page 363 of your report a derivative of DLTDP? And that is formed with a reaction with formalin that also show up on your PYMS data.

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A. Well, it's an OH group. So this compound would have potentially the problem -- the possibility of reacting with formalin, but this branch point tells me it's not.
When you get fatty -- they make this from fatty acids. When you extract fatty acids from the body, you're going to have C12, C14, C16, C18, all of these. They make the mixtures of fatty acids down, and then they react to fatty acids with the sulfur-containing alcohols to get the final compound.
So when you're all said and done, what you have is this compound plus two carbons minus two carbons, plus or minus. You don't have this structure.
If this hydrolyzed here --
Q. At 12.7 minutes?
A. Yeah. But this might --
MR. THORNBURGH: Let him finish the answer.
A. You would have something akin to this, but you wouldn't have this because you don't have the branch point. That's linear. That's branched.
Q. I thought you told me that this showed up at 7-point-something minutes.
A. It does. It does. That's what this is telling me up here.
Q. And this is -- could be -- you don't know for

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sure -- a derivative or a compound formed by formalin and DLTDP?

MR. THORNBURGH: Objection. Move to strike. Misrepresents his testimony.

THE WITNESS: What do I do now?

MR. THORNBURGH: Answer it the way you just answered it for him.

A. Well, this doesn't represent this.

Q. I didn't say that. That's not my suggestion.

A. Well, it can't be from this, then, because this isn't linear and this is. It's a different chemical structure.

Q. So what you're telling me, just so I understand, the substance depicted on the bottom of 363 cannot be derived from the dilauryl thiodipropionate that's shown on page 1386?

A. Correct. If it was just this, I could say maybe, because the hydrolysis here would give this functionality. But it wouldn't give this branch.

Q. Okay.

A. And the branch isn't there.

Q. The branch you're talking about is at the very end of the molecule there's a figure going straight up?

A. Right.

Q. Okay.

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A. That represents two methyl groups versus one, to a chemist.

Q. That's the best I can do. Sorry. Thank you.

Is the chemical structure at the bottom of 363 --

A. Can I put these -- okay. Keep these.

Q. 363, is that pure DLTDP or a derivative of DLTDP?

MR. THORNBURGH: Objection. Asked and answered. Objection. Compound question. Objection. Misrepresents his testimony.

A. It doesn't represent anything from dilauryl thiodipropionate because of the branch, like we just talked about.

Q. Okay.

A. Can these go back now? Do you want more?

Q. I don't want any more of that.

A. Okay.

Q. Let's go back to page 69, please.

A. Got it.

Q. What information do you have that these eight substances on page 69 contribute to environmental stress cracking in Prolene?

A. Well, their presence is just generally recognized as contributing to environmental stress

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cracking in Ethicon's own research documents.

Q. Have you ever tested these materials to determine the extent to which they can cause environmental stress cracking in Prolene polypropylene mesh?

MR. THORNBURGH: Objection.

A. I'm relying on published information, Clave and Ethicon's own documents.

Q. Do you have an opinion to a reasonable degree of certainty that any or all of these eight substances caused environmental stress cracking in Miss Bellew's polypropylene mesh?

A. Anytime they're present in an oxidized material, they're going to contribute to environmental stress cracking to a reasonable degree of scientific certainty.

Q. And what literature is one on which you rely to support that position? I think you said the literature support it.

A. Well, Clave talks about it.

Q. I want to get to Ethicon's documents later. I understand that's an aside. I asked for published literature. That's what I'm interested in. I'm just trying to be fair on the time.

Is there any published literature?

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MR. THORNBURGH: Doctor, feel free to look at your report if you need to refer to it.

A. Well, Clave, I think Celine Mary.

Q. Doctor, do you know the extent to which the substances that are on page 69 of your report, these eight substances that you've identified, are plasticizers?

A. They would be considered plasticizers, yes.

Q. Do you know how these eight substances, which could be considered as plasticizers, could operate to make the Prolene polypropylene mesh tougher?

A. Well, plasticizers do tend to do that in amounts. But generally the amounts for plasticizers are huge. You plasticize PDP, you put in -- what is it? Polyvinylchloride -- excuse me -- pipe, which is very rigid. You turn it into a flexible purse.

But the amount of plasticizer -- and there's 40, 50, 60, 70, 80 percent. We're not talking anything like that here.

Q. Have you ever analyzed the extent to which the presence of these eight substances identified on Table 9, page 60 of your report, would operate as plasticizers and toughen the Prolene polypropylene mesh in Mrs. Bellew?

MR. THORNBURGH: Objection. Asked and

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answered.
(Record read)
MR. THORNBURGH: Objection. Asked and answered.
A. Again, I'm relying on -- I have not personally. I'm relying on Ethicon's own studies --
Q. Okay.
A. -- that says you get -- I'll read it to you. Better if I read it than get it wrong. Average breaking strength --
Q. Before you read that, would you mind identifying the article by the number at the bottom?
A. ETH MESH 15955462.
"The average break strength remaining for size 30 is 76.5 percent, range 47 to 93 percent. For size 4.0 is 98.2, range 86 to 110 percent, when compared to similar sized controls.
"Only one length of 50 Prolene was available for tensile strength measurement, indicating 76 percent strength remaining for the 7-year specimen."
So I don't know. We claim that strength is going up, but this claims it goes down with time. It's Ethicon's own document.
Q. Have you seen any documents addressing the eight substances that are present on Table 9 on page 69

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as to whether they operate as plasticizers in Prolene polypropylene mesh?
MR. THORNBURGH: Objection.
A. Again, Clave I think talks about them getting into the -- getting into the polymer but not as a plasticizer, as a stress cracking agent.
Q. Is that the extent of your literature knowledge of the impact of these substances on the Prolene polypropylene?
MR. THORNBURGH: Objection. Do you want him to talk about internal documents now or not?
MR. THOMAS: I thought he just did.
A. It goes to environmental stress cracking.
MR. THORNBURGH: I think that's what his question was. Listen to his question.
Q. I'll withdraw the question if you're going to go through those documents right now. I'll look at those later if that's okay. Withdraw the question.
Now, when you -- Strike that.
The presence of these eight samples -- Strike that.
The presence of these eight substances would tend to, on a relative basis, reduce the percentage presence of the other components to the sample. Would you agree with that?

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MR. THORNBURGH: Objection.
A. Other components of the sample like what?
Q. For example, polypropylene. Before these eight compounds became part of the polypropylene, the polypropylene was 100 percent. When these eight samples were introduced in the polypropylene, the percentage of polypropylene is then reduced?
MR. THORNBURGH: Objection.
A. Yes, but the amount is so tiny as to be irrelevant.
Q. And we've already established that you've not measured the amount of these eight substances.
Can you give a reasoned judgment about how much of this -- of these eight materials are present in the Bellew sample as a percentage and then explain to me how you make that judgment?
MR. THORNBURGH: Objection. Compound, form, mischaracterizes his prior testimony.
A. I think I've explained this before. But the peak size and all, it's -- PYMS and LCMS are extremely sensitive techniques. The fact that you can see a peak -- you can see peaks at parts-per-million levels.
So I would say that all of these quantitatively should be below a 10th of a percent, probably just on my general knowledge, experience, based on years of work

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with these techniques.
We're seeing very tiny peaks, much less than those that we see for your .4 percent dilauryl thiodipropionate or the Santonox R. So it certainly is not -- it's a trivial amount.
Q. Okay. What does "trivial" mean?
A. It's an amount that would have no effect as a plasticizer at all.
Q. Okay. On your nanothermal analysis, page 82 --
A. 82. Okay.
Q. It looks like you're missing a sentence --
MR. THORNBURGH: Objection.
Q. -- right in the middle of the paragraph.
MR. THORNBURGH: Objection.
Q. At least mine is.
A. The "nano" should be capitalized. It's the start of a sentence. "Nano-TA measurements, Figure 83 (right) on these flakelike materials show an even lower thermal transition than observed for the Bellew sample."
That's a complete sentence. It just needs a capitalization of the "nano."
Q. Now, in a nanothermal analysis you did the AFM imaging, AFM analysis. And that's where you arrived at the approximate 1 micron in size. Correct? Is that fair?

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A. Where are you, sir?
Q. I'm on page 79 and 80.
A. Okay. And now the question? I'm sorry.
Q. Figure 80 shows your analysis of the surface of the Bellew, Dianne B sample and shows a crack depth measured that one time in that one place at 1,178 nanometers. Correct?
A. Yes.
Q. And that's what we've been referring to throughout the day as the 1 micron crack?
A. Correct.
Q. Did you conduct the same kind of testing on the mesh cleaned with sodium hypochlorite?
MR. THORNBURGH: Objection.
A. We didn't do a crack depth there, no.
Q. Why?
A. I have no idea. We really weren't after cracks anyway. We were after melt points. So it was really a secondary -- there was no reason not to, no reason to do it either.
Q. Was there anything about sample availability that limited your opportunity to test for crack depth on sodium hypochlorite-treated explant?
A. I wouldn't think so. You can see the flake there on Figure 83 that -- the red sections. There's

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actually two flakes marked in red hash marks versus the solid material, which is in blue. It's got two different melt points.
Q. Okay. Now, on page 83, when you talk about, the second and third line, "significant surface degradation," again, we're talking about, at least as far as you know, a 1 micron crack depth?
MR. THORNBURGH: Objection.
A. I don't follow, 1 micron crack depth.
Q. Let me ask the question this way: What is the significant surface degradation you're talking about? Is it the --
A. Well, it's the melt point, 115 versus 78.
Q. Got it. Which we went through in great detail?
A. Which we went through.
Q. And it's 1 to 2 percent?
A. Degradation would result in the 4200 molecular weight.
Q. Okay. And page 83, Figure 83, the image to the left with the blue is designed to show those places where the measurements were taken. Is that fair?
A. The red and blue is where the measurements were taken. Correct.
Q. And the lines on the graph to the right are reflections of what the measurements showed?

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MR. THORNBURGH: Objection.
A. Well, the top and the left are the dimensions of the surface, the X and the Y.
Q. Okay.
A. So the top one, 0 to 10, is microns. And on the left side it is also microns, 0 to 20. The bottom one, minus 1,000 to 1,000 nanometers is the hike.
So you can measure the surface by the color. Light materials are elevated. You can see the color at the bottom with the scale. So it's scaled according to color. Do you see that?
Q. Yes.
A. So 1,000 nanometers above the surface would be white, and 1,000 nanometers below would be that black.
So in one sense you can see a height differential here approaching two microns, 2,000 nanometers, in this sample from top to bottom. Some regions are higher than others.
Q. Is there any way to tell from this analysis what the chemical composition is of the sites that are tested by this test?
A. It's only designed to do melt points.
Q. Right. So is it fair to understand that you can't tell me to a reasonable degree of scientific certainty that what is tested in Figure 83 is only

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polypropylene?
MR. THORNBURGH: Objection.
A. That question would be answered by Figure 60. The infrared shows that the hypochlorite treated was polypropylene, oxidized polypropylene. So it's oxidized polypropylene.
Q. All right. Without any kind of contaminants at all?
A. Well, there's the carbonyl. There's the oxidation piece we showed you. And of course, there's those couple identified peaks where something else has reacted. We don't know what it is, but it's reacted polypropylene.
Q. How do you know it's reacted polypropylene?
A. That's all that's there. We can go back and look at that again if you want.
So we start out on 59, Figure 58, with the mesh that's got the protein on it. Can you see amide I and amide II bands? And then it's treated with hypochlorite. Turn the page. And the amide I and the amide II is totally gone and what's left is water, identified by that 3500 band. Oxidized carbonyl, 1720, 1740, and that sideband, 1710. And there's a 1750 which I can't identify.
And then the 1454, 1377 are propylene bands.

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And all those little bands at 1165, 999, 972, 841 are all polypropylene, which are very, very weak. And the fact that they're so clear there is -- it makes it look very similar to the spectrum of a pure polypropylene, which is back there a couple of charts.

If you go back and look at 55, you'll see a pure polypropylene. And that spectra we have there is essentially pure polypropylene.

So except for the oxidation bands and that little bit of unidentified, everything else in the spectrum is polypropylene, plus a little bit of water, when you compare 55 and 60.

Q. Let's go to page 84 of your report, please.

The last paragraph says, "It can be stated to a reasonable degree of scientific certainty that degradation in these fibers is a surface phenomenon initially, which will more likely than not continue deeper and deeper into the fiber as time passes."

The last part of that sentence is what I'm interested in.

There's no evidence from the work that you've done in this case that the degradation that you've described here was more than a surface phenomenon on Ms. Bellew. Correct?

MR. THORNBURGH: Objection.

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A. In Ms. Bellew, yes.

Where are you reading here? Page 84?

Q. Yes.

A. Which paragraph?

Q. Third paragraph.

And then you say after that that "more likely than not continued deeper and deeper into the fiber as time passes."

A. Right.

Q. I've not seen any analysis in your report to explain how that happens.

MR. THORNBURGH: Objection.

A. It happens the same way that the surface layer degradation happens. It takes longer because it's further in. The inside is more crystalline, and so it's less susceptible to degradation in general. But it will slowly occur.

That's based on my 40 years of experience doing testing. I've seen this over and over again.

Q. 40 years of testing of what?

A. All kinds of plastics, including polypropylene. I remember doing a stadium seating problem in Japan where literally 100,000 seats turned to dust and blew away, all polypropylene, because of lack of antioxidant. It went right through the surface layer, went to the next layer, went to the next layer, went into the next layer. Within less than two years, every seat was just gone.

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Q. Have you undertaken to determine how long Prolene polypropylene in the Prolift device will last in the human body before it fails?

MR. THORNBURGH: Objection.

A. Have I?

Q. Yes.

A. I think that's determined by the doctors and the women who decide when the pain and all that is -- that's not my area of expertise.

Q. Okay. Have you undertaken any analysis to determine how long the Prolene polypropylene in TVT lasts before it fails, as you've described in this report?

MR. THORNBURGH: Objection.

A. Again, the failure would be determined by the doctors and their patients.

Q. You can't do that?

A. They have to decide when the pain is too great or whatever is going wrong, not me.

Q. In terms of the mechanical properties of the Prolene polypropylene mesh, have you undertaken to determine when the Prolene polypropylene fails because of the degradation that you've described in this report?

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MR. THORNBURGH: Objection.

A. Well, Number 1, we just don't have enough material to do physical testing. None of us do, either side.

And Number 2, the failure, again, is determined by the doctors and the patients, not me.

Q. Okay. How long have polypropylene sutures been used in the medical field?

MR. THORNBURGH: Objection.

A. They were used in the dog studies. So I don't know exactly how long, but many years for sure. Back in the '80s at least.

Q. Do you have an opinion to a reasonable degree of scientific certainty as to whether the cracks stopped after what you've described as penetration of the surface of a few microns deep?

MR. THORNBURGH: Objection. Asked and answered.

A. Well, what you obviously get from Iakovlev and the studies that I've seen from Dr. Thames is that there's this bark -- I can't pronounce this. Iakovlev. There's the bark. And then Thames shows something similar. We see it in our SEM micrographs as well.

What seems to happen is there is a rather

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rapidish failure of the surface, a few micron layer, and then the other layer underneath would start to go, but it would be much slower.

So there will be a point at which the rate of degradation -- I guess if you want to call it that -- would slow down once the surface is fully destroyed, and then you're at the underlying crystalline layer that's going to degrade but much slower. Nobody has kept them in long enough to study that chemistry.

Q. How long would you need to keep them in before you could study that chemistry?

MR. THORNBURGH: Objection.

A. Since it's not been done, I don't know.

Q. What is it chemically that is the difference between this outer layer and the inner layer that causes a distinction between the two layers, as you've described it?

A. I'm not sure it's a chemical difference. It's a physical difference.

Q. Tell me what you mean by that.

A. You have an amorphous layer that's a few microns deep, as described in the Celine Mary article and in your own experts, your own people's discussions. And then you have a solid and a core.

And that outer core is susceptible -- much more

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susceptible -- the outer core is more susceptible because it's amorphous. And the antioxidants can bleed out faster and the stress cracking agents can bleed in faster. The tie molecules then can rupture and start the process to degrading the surface.

Q. Do you know -- Strike that.

Do you have any way to determine the relative physical differences between the outer layer and the inner core that you've just described?

MR. THORNBURGH: Objection.

A. Well, physical differences?

Q. I've tried to use your word.

A. You can measure the melt point. The melt point is much lower, as shown in nano-TA of the surface. It's 175 initially and then it will degrade quickly to the 120s, 115, 78.

Q. And how does that compare to the melt point of the interior portion?

A. Well, that was done by DSC. And we showed it this morning as 164, 165.

Q. Can you use --

A. It stayed constant. Sorry.

Q. I'm sorry. Can you use DSC measurements of melt point as a comparison of apples to apples if you use a DSC melt point of the inner core with a

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nanothermal melt point of the outer layer?

MR. THORNBURGH: Objection.

A. It's apples and oranges because you're measuring the nondegraded inner core primarily with DSC. You are measuring the outer core, but it's diluted because it is a thin-skin effect. Again, it's a total gross phenomenon.

Q. I hope you understood my question. Let me try again. I'm trying to understand if it's appropriate to use --

MR. THORNBURGH: He answered the question.

Q. I thought you said it was inappropriate to use the outer layer nanothermal analysis and compare it to the inner core measured by DSC.

MR. THORNBURGH: Objection.

A. Well, the DSC gives you a blended --

Q. I see.

A. -- response from both the skin and the inner core. But most of the melt point is determined by the inner core, whereas nano-TA is exclusively outer skin.

Q. Okay. And the reason why it would be apples and oranges is because you're essentially measuring the outer layer both times?

MR. THORNBURGH: Objection.

A. The damaged outer layer versus the intact inner

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core with the damaged outer skin on it.

Q. Okay.

(Recess taken)

BY MR. THOMAS:

Q. Doctor, I want to hand you what I've marked as Deposition Exhibit Number 14. This is your invoice that you've sent to Anderson Law Offices, dated July the 9th, 2014. Is that correct?

A. Yes.

Q. Our conversations off the record suggest that this is the -- as I understand it, anyway, the total amount of time that you've spent -- Strike that.

Is it fair to understand that Jordi Number 14 represents your billing not only for the testing that's reflected on that invoice but also for the preparation of your reports in both New Jersey and in Bellew?

A. Yes.

Q. Okay.

A. We don't bill extra for writing reports. That's included in the cost of the analyses.

Q. Okay.

A. Unless there's something exceptional about it.

Q. Do you know if this is the only invoice that you've submitted for both the Bellew and New Jersey expert reports?

A. I think you have everything that's been billed. That's all I can tell you.
Q. You mentioned there would be some preparation time since July 9th, 2014, where you prepared for the deposition in this case?
A. That's correct. We have not billed that yet.
Q. And how much time have you spent preparing for the deposition in this case?
A. Let's say 40, 45 hours for me, and then maybe Adi will have a few hours of prep time with me as well.
Q. What did you do to prepare for your deposition in this case?
A. Went over all of these materials.
Q. Anybody work with you other than Dr. Kulkarni?
A. No.
Q. I ask that when you do submit your next invoice that you supply us a copy, please.
MR. THORNBURGH: Sure.
Q. Do you agree that calcium stearate has a carbonyl band?
A. Yes.
Q. Would you look at page 233 of your report, please?
A. 233?
Q. Correct. It's not a number on the page.

A. Is it Figure 233 or page?
Q. Page. Right before PYMS. It's in your FTIR data. It's the last page.
A. I'm looking for a page number here.
Q. Mine doesn't have a page number on it.
A. I have 231, 232, 233.
Q. Do you see the peak on that FTIR spectra at 1741.6?
A. Yes, I do.
Q. Can you rule out the DLTDP as not causing this peak?
MR. THORNBURGH: Objection. Asked and answered.
A. The DLTDP is not causing it?
Q. Pardon me?
A. The DLTDP is not causing it?
Q. Yeah. You told me before -- I didn't want to ask the same question again.
A. That's all right.
Q. I'll ask them again so that there's a proper predicate.
The DLTDP also has a carbonyl peak?
A. Yes, sir, it does.
Q. And fatty acids and lipids also have carbonyl peaks?

A. Yes, they do.
Q. And we just established a minute ago that calcium stearate has a carbonyl peak. Correct?
MR. THORNBURGH: Objection.
A. Has an acid carbonyl, yes.
Q. How can you rule out that what appears at 1741.6 on page 233 of your report is not DLTDP?
MR. THORNBURGH: Objection. Asked and answered.
Go through it again.
A. The .04 percent is what we found of residual dilauryl thiodipropionate that was extracting in the additives. And there's virtually none there.
Q. Okay.
A. You've got to have a 1 percent level to see it. We're seeing it at trivial levels.
Q. How can you rule out the calcium stearate did not cause the 1741 peak?
MR. THORNBURGH: Objection. Asked and answered.
A. Again, the hypochlorite will tend to destroy. Only small molecules will oxidize them. Again, what's the level to be put in to begin with in the mesh? It's -- I don't remember the recipe. It's tiny.
Q. Is your opinion based upon the sodium

hypochlorite taking out the calcium stearate?
MR. THORNBURGH: Objection.
A. Partly that and partly the fact that it's had time to leach out. As Dr. Barbolt clearly says in his deposition, agrees with us that it does, the additives leach out. If they leach out, they can't be there to cause a carbonyl band to see.
Q. Have you determined how fast or at what rate the carbonyl stearate leaches to?
MR. THORNBURGH: Objection.
A. No.
Q. How can you rule out that fatty acids or lipids are not causing the 1741 peak?
MR. THORNBURGH: Objection. Asked and answered.
A. The same answer we gave before. That is, the levels are so low, PYMS and LCMS, that they wouldn't show up in infrared.
MR. THOMAS: Mr. Hutchinson is going to take over from here.
(Off the record)
(Whereupon Mr. Thomas left deposition)
EXAMINATION
BY MR. HUTCHINSON:
Q. Dr. Jordi, I want to ask you a couple followup

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questions.
Do you believe that a crack that is 1 micron in depth will have a strong impact on mechanical property of stiffness?
MR. THORNBURGH: Objection.
A. Of the localized area, yes.
Q. How so?
MR. THORNBURGH: Objection.
A. Well, if you take a -- I don't know -- take a piece of glass and have it cut into cracked pieces, it's certainly going to affect its mechanical rigidity of the piece. But it's only at the level of the cracks, too. It's not of the entire fiber. This is a surface -- we said all day long, it's surface degradation.
Q. What about the mechanical property of elasticity? Do you think a crack that's 1 micron deep will have --
MR. THORNBURGH: Objection. He's already answered these questions.
MR. HUTCHINSON: I'm asking about elasticity. The word "elasticity" hadn't even been used.
MR. THORNBURGH: Yes, it has. We can go back and look in the transcript.
MR. HUTCHINSON: I understand.
MR. THORNBURGH: The questions have been asked

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and answered.
MR. HUTCHINSON: It's not going to --
MR. THORNBURGH: This is not fair to the witness for you to come back in here and start asking the same questions that have been already answered and asked by your colleague, who's had an opportunity to ask additional questions. He's moved on, now probably 150 pages back in the transcript. So it's unfair for you to come in here and try to play this game.
MR. HUTCHINSON: I understand. Last question.
BY MR. HUTCHINSON:
Q. Will it have a strong impact, Doctor?
MR. THORNBURGH: Asked and answered.
A. I'm sorry. Can you repeat?
Q. Will a crack that's 1 micron deep have a strong impact on mechanical property of elasticity?
MR. THORNBURGH: Objection. Asked and answered. Also mischaracterizes the other evidence that's in this case.
A. In the region of the crack, surely.
Q. Okay. Doctor, I want to make sure I have an understanding of what we did on the board. If 1 percent --
MR. THORNBURGH: Objection. We've already -- Dave Thomas has already covered this question. He's

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already asked these questions about this formula.
MR. HUTCHINSON: No, he didn't ask all the followup questions. You haven't even heard my question yet. Don't get all mad at me, Dan.
MR. THORNBURGH: You said I was sexy when I was mad or cute.
MR. HUTCHINSON: Actually, I didn't use the word "sexy." That's a gross mischaracterization of my testimony. Just listen to my question before you make an objection.
MR. THORNBURGH: Objection. Move to strike. This is unfair to the doctor. Go ahead.
BY MR. HUTCHINSON:
Q. Dr. Jordi, if 1 percent of the propylene monomers oxidize, then that will give 16.66 oxidation sites. Correct?
MR. THORNBURGH: Objection.
A. In a 70,000 molecular weight polymer to start with.
Q. Good. So if I understand this correctly, then the 16.66 represents less than 1 percent of the oxidation sites in the 70,000 molecular weight --
A. Do you want to know what the 16.66 represents?
Q. No. Answer my question first.
MR. THORNBURGH: Objection. Your question

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doesn't make sense.
Q. I'll withdraw the question.
What does the 16.66 represent?
A. Yes, the number of oxidation points.
Q. Out of the 70,000 weight --
A. Correct.
Q. Okay. And that was a 70,000 oxidation --
A. No.
Q. Would it be 70,000 potential oxidation sites?
MR. THORNBURGH: Objection.
A. No, because you've only got -- the molecular weight of the monomer is 42. So you have to divide the 70,000 by the 42. There's 1,666 potential oxidation sites. Each monomer has a potential to oxidize. A monomer doesn't weigh 1; it weighs 42, in this case.
Q. Thank you. Doctor, can you draw out the chemical structure of how a polypropylene polymer degrades?
MR. THORNBURGH: Objection.
A. That's done for you in my report, I believe.
Q. What page is that?
A. Let me look it up, sir. Pages 3 and 4. RH on page 3 represents the polypropylene pristine.
Q. Okay.
A. And if oxygen interacts with it, it can form

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peroxide, ROOH.

These are what we call initiation reactions for degradation. Another initiation reaction would be for oxygen to extract a hydrogen radical, leaving a radical R dot and a HO2 dot radical.

Finally, peroxide can split disproportionate into an RO dot radical and a hydroxide radical and/or an oxygen can insert in the radical to form ROO dot. Those are all radicals.

And then propagation is where those radicals attack fresh polypropylene, the RH again, and interact with it. Those are the propagation reactions.

Q. Okay. Doctor --

A. And then the last page gives the termination coupling steps which end the process. And that hydroxide radical also can react with a polypropylene to form water in an R dot radical.

All these reactions occur. So for example, the ROH on the bottom of page 3 would mean we could see alcohols. And you do see alcohols in polypropylene degradants.

Q. Dr. Jordi, can you draw for us -- and I'm not talking about what's referenced on page 3. I'm talking about, can you draw for us the chemical structure with polypropylene cleaved to produce a carbonyl group?

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MR. THORNBURGH: Objection.

Q. Can you do that?

MR. THORNBURGH: Objection.

A. I know where to get it. It's in the standard textbooks.

Q. I understand. But, Doctor, sitting here today, is that something you can't do? Is that correct?

MR. THORNBURGH: Objection.

A. I would need to refer to the textbook. I know right where to get it.

Q. But am I not correct that sitting here today you can't do? Correct?

MR. THORNBURGH: Objection.

A. It's just going to be rearrangement of these molecules to get it.

Q. But my question is, Doctor, sitting here today, that's something you can't do without referring to the book. Correct?

MR. THORNBURGH: Objection. You're asking him to --

MR. HUTCHINSON: I'm asking the witness a question.

MR. THORNBURGH: Let me see if I understand the question.

MR. HUTCHINSON: Whether you understand the

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question or not is unimportant.

MR. THORNBURGH: Madam Court Reporter -- yeah, it is important. I'm here to protect the witness.

MR. HUTCHINSON: Dr. Jordi, you can answer the question.

MR. THORNBURGH: Madam Court Reporter, can you read back the original question.

(Record read)

MR. THORNBURGH: Objection.

A. Number 1, it doesn't cleave initially to form a carbonyl group. It forms a carbonyl group, and then later oxidation steps lead on to form acids. You go from a carbonyl to acids. Other chemical -- There's a whole process of reactions.

Q. I understand. But, Dr. Jordi, my question is, can you draw for us the chemical structure? Yes or no.

MR. THORNBURGH: Objection.

A. Of carbonyl?

MR. THORNBURGH: Your question doesn't make sense. It's an unscientific question.

Q. I understand. Let me make sure you understand my question.

Can you draw for us the chemical structure with polypropylene cleaved to produce a carbonyl group? Can you do that somewhere?

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MR. THORNBURGH: Objection.

A. That's a wrong question. It doesn't cleave when it forms an initial carbonyl group.

Q. Why not?

A. Because it is not an end product of oxidation. It is a part of a process of oxidation.

Q. You will agree that you have to have a cleavage in order to begin oxidation. Correct?

MR. THORNBURGH: Objection.

A. Not to begin. That's the end product of oxidation.

Q. The end product. All right. Doctor, can you explain to us how there was a cleavage for Miss Bellew's explant that caused the -- that ultimately caused oxidation?

MR. THORNBURGH: Objection.

A. The cleavage didn't cause the oxidation. The oxidation caused the cleavage.

Q. Okay. Can you draw for us that chemical structure of the oxidation causing the cleavage?

MR. THORNBURGH: Objection.

A. Well, it would be polypropylene monomer.

Q. I tell you what --

MR. THORNBURGH: Hold on. Let him finish.

Q. Instead of drawing on the white board, can we

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do it on a clean sheet of paper? Would that be easier? So I can look over your shoulder.
A. You can write it down here, can't you?
Q. I'd like you to do it --
MR. THORNBURGH: Do what you're doing, Doctor. If it makes him feel more comfortable, then we can copy it.
A. We can copy it.
MR. THORNBURGH: Not a big deal.
Q. Fair enough.
A. There's three functional groups -- well, carbons in a polypropylene monomer. And then you would have another CH2. And then would you have a carbonyl here that would have formed, CH3. So you'd have something like that. That's one of the reactions. There's a whole slew of these reaction products. I got to show you the tables of these things.
Q. What I don't want you to do is, I don't want you to have to write all of this on the board and then transpose it to a sheet of paper. So if we can work from this sheet of paper?
MR. THORNBURGH: Objection.
A. Why don't I give you a Xerox sheet from the textbook?
MR. THORNBURGH: Let the record reflect that

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Dr. Jordi drew out the molecular structure of polypropylene that's been oxidized. But as he testified to, there are many different reactions that can occur. And of course, he's not going to sit here and draw all of those different reactions.
BY MR. HUTCHINSON:
Q. And Dr. Jordi, just so we can have a clean record, could you draw for me what you've drawn on the board as what you illustrate to be the chemical structure, please.
A. Can I show you the book or --
Q. I would like for you to do that, please.
MR. THORNBURGH: Let the record reflect that counsel for the defendant will not allow Dr. Jordi to refer to any books, so Dr. Jordi has drawn out molecular structure based on his -- based on the question -- the original question, which was unscientific to begin with.
(Pause)
MR. THORNBURGH: Can you recite for me the fourth amendment verbatim as it is in the constitution, or would you need to refer to the constitution to make sure you got it exactly right? This is ridiculous.
MR. THOMAS: I am not holding myself out as a constitutional scholar.
MR. THORNBURGH: Restatement 3rd. Can you tell

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me what Restatement 3rd says? Nope.
(Pause)
MR. THORNBURGH: I'm objecting to this exercise. Move to strike.
(Pause)
A. This is just one potential product that's not -- certainly isn't by any stretch the only possibility, but there is the insertion of a ketone in the backbone of a polypropylene chain.
Q. Okay.
A. Carbonyl.
Q. So for my benefit, could you explain to the jury what you have just drawn here and what you actually scratched out, please.
MR. THORNBURGH: Objection.
A. Well, I put in three polypropylene monomers, 1, 2, 3, with the third one oxidized with carbonyl in it.
Q. Okay. And what did you scratch out at the top of Exhibit 15?
A. I put the methylene group, methyl group, one carbon too quickly at the top. So I scratched it out, started over.
Q. Doctor, can you show me where the cleavage of the molecule is, please --
MR. THORNBURGH: Objection. Scientifically

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invalid.
Q. -- with a red pen.
A. Well, a carbon can only have four bonds to it. There's 1, 2, 3, 4. So this is the break point right here in terms of the monomer.
Q. In terms of the monomer. Is that what you're testifying?
A. Well, it's a break point in the chain. That's three monomers but hooked together. Polypropylene, there would be a thousand of these.
Q. So what would be on the right side of the break that's represented by --
A. Another polypropylene chain.
Q. And, Doctor, what caused this cleavage, which you've indicated as a red line, to occur?
MR. THORNBURGH: Objection.
A. It's called a chemical rearrangement.
Q. But what caused that to occur?
MR. THORNBURGH: Objection.
A. Radical reactions.
Q. For Miss Bellew, what caused it to occur?
MR. THORNBURGH: Objection.
A. Radical reactions for peroxide and from these reaction chains that I draw on pages 3 and 4.
Q. Doctor, have you had a chance to review

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Dr. Thames's expert report, which has been marked as Exhibit 5?
A. Okay.
Q. Have you had a chance to review that?
A. Yes.
Q. And I would prefer not to go page by page and line by line, but if we need to, we can.
What do you take issue with that Dr. Thames has included within his report?
MR. THORNBURGH: Objection. What time is your flight at?
A. I don't even know how to answer that. There's so many of them.
Q. Doctor, what are your major disagreements as reflected in Dr. Thames's report?
A. I don't believe there's a protein coat. He does. I believe it's easy to remove. He believes it's hard to remove. It says "In conclusion," page 4, "I do not believe that Ethicon's Prolene undergoes meaningful or harmful degradation in vivo."
I do. The infrared oxidation. I've shown the melt point reduction, nano-TA. Showed the lowering of antioxidant levels.
Q. Doctor, do you have any criticisms of Dr. Thames's stress-strain curves indicated on page 5?

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MR. THORNBURGH: Objection.
A. No.
Q. That's a concept you agree with?
A. Yeah.
MR. THORNBURGH: Objection.
Q. What else? Let's look at page 7, Doctor. Do you have any criticisms of Dr. Thames's plot of the Burkley seven-year dog study data?
MR. THORNBURGH: Objection.
A. It may be true, but it's kind of irrelevant because we couldn't do it on the mesh. He didn't have enough sample to test. I didn't either.
And these samples are sutures which are structurally very different. They're much thicker. They don't really represent -- A thin-skin degradation on them is not going to affect the structure overall anywhere near the degree it's going to affect the mesh. It's only 100 microns across.
Q. Do you have any criticisms of Dr. Thames's plot of the seven-year dog study data?
MR. THORNBURGH: Objection. Asked and answered.
A. If you're talking about sutures, then he had enough material to test.
Q. Okay.

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A. I differ with his -- on page 8, I differ with his concept that TPC had little to no macromolecular weight. Well, no. "In that little to no macromolecular weight degradation was noted,."
I agree with that statement. Macro. We're claiming there was degradation on the surface.
Q. Okay.
A. Page 9, he says, "Had degradation occurred, there would have been a significant loss in toughness of molecular weight and a concomitant increase in carbonyl frequency, none of which occurred during the seven-year dog study."
What on earth that had to do with the meshes is beyond me.
We saw cracked polypropylene. We saw an increased carbonyl. We saw a loss in the melt point, which correlates with a drop in the molecular weight. I don't know how much more we need.
So he said, "Had degradation occurred, there would have been a significant loss in toughness and molecular weight, and there was a great loss in molecular weight."
Toughness, I have no way to judge because I couldn't test it.
Q. Okay. Doctor, do you agree -- moving to

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page --
MR. THORNBURGH: I'm not sure he's done.
A. You said go through the whole thing.
Q. Okay. Please.
A. I don't know.
MR. THORNBURGH: That was your request.
A. "It is my opinion, supported by experimental results, that these proponents," page 9, "have historically, and erroneously, identified biofilm as polypropylene. Biofilm forms in vivo and is fixed by the chemical reaction of formaldehyde with proteins. Thus, these proponents have mischaracterized biofilm as polypropylene."
And to date, the scientific and chemical basis of their argument is nonexistent.
FTIR of the shards and the surface in the Bellew case clearly showed it was polypropylene. And when we removed the protein with the sodium hypochlorite, it became essentially pure polypropylene.
It says the proponents, which is basically the vast majority of people in the literature, including the gentleman who invented polypropylene that we've talked about his melt point curves, the NATA paper.
So basically what he's doing is saying that Nobel Prize winners and virtually everybody in the

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literature doesn't know anything, but he's the only person who's right and capable of judging. I couldn't disagree more strongly.

Q. Okay.

A. "Mischaracterized biofilm as" -- we removed the supposed biofilm with sodium hypochlorite. It's not there. We have a clean polypropylene by IR. I don't know what he's talking about. It's baloney to me.

MR. THORNBURGH: Keep on going, Doctor. Answer his question to the best you can sitting here, all your criticisms of Dr. Thames. Keep on going through.

A. "This generalized process," page 10, "was followed by a number of investigators cited in these matters such as Celine Mary, Clave, Liebert, Costello, Ostergard, Jordi, Iakovlev, Rosenzweig, Klinge, Ducheyne, et cetera. However, none considered the presence of the hard, brittle, and insoluble shell of the protein-formaldehyde polymer surrounding the explanted mesh and" --

That's a boldface lie. We removed the protein coat. I showed you that today. It's just not true.

"This well-known basic" -- it is well-known, I'll give him that. "This well-known basic chemical reaction was missed by these investigators, authors, and apparently many others."

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He's the only one in the world who knows how to characterize it, presumably.

"As a result, significant amounts of unreliable and confusing data now permeate the media with regard to mesh explants and their propensity for surface cracking."

I couldn't disagree more. We can see the cracks. We can see the extrusion lines in the cracks right through the flake material. And if you want to see one, I've put down page 113. Let me show you that one so you can see it for yourself. Page 113.

(Pause)

A. Do you want me to come over to you or you can come to me and I'll point it out to you so it's quicker? Yeah, that's it.

These are extrusion lines. And they're seen up here right through the cracked pieces as well. Right up here through the cracked pieces.

So when the cracked pieces come off, they have to be polypropylene because they're part of the original extrusion. Not protein coat. It can't possibly be. And it's obvious.

MR. THORNBURGH: Do you want us to keep going through page by page?

A. Do you want to still go on?

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Q. Uh-hmm. I want to know all your criticisms about Dr. Thames.

A. I don't know if this is all of them. It's just the ones I'm catching.

Q. Dr. Jordi, I can simplify this for you. You don't have to go through this page by page, but I want to know all of your major criticisms of Dr. Thames' analysis.

A. I have to respond to his comments, sir. I'm sorry.

Q. Fair enough. However it is easiest for you.

A. I haven't memorized his whole report. That's my point. Without looking at it -- "It's well-known and uncontested that polypropylene formulated without antioxidants are subject to oxidative degradation."

True. I agree with that.

"However, it is equally known that Ethicon properly protects its Prolene products with antioxidants."

I agree with that.

"At the time of this writing I have seen no scientifically sound evidence to prove Ethicon's Prolene oxidizes in vivo."

Well, we've shown infrared. We've shown drop in molecular weight through the carbonyl bands, through

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the nano-TA. So I don't know what he's talking about.

"LCMS data show lack of antioxidants."

And Liebert says with a lack of antioxidants it's going to degrade mas does virtually everybody else, as does the leaching effect -- I don't see -- from Liebert and Barbolt, which is one of -- was one of Ethicon's own experts. So apparently he disagrees with Ethicon's own experts as well.

"Infrared spectrum. Mechanical testing of implanted and nonimplanted filaments containing an antioxidant show no changes in chemical or physical properties as a result of implantation."

To my knowledge, neither of us have had enough sample to run any physical testing on, so this is baloney. What's he tested? I'd have to see data. There is no data. There's just a raw statement, unsupported.

His statement, "The results from SEM, DSC, TGA compliance testing provided strong support" --

Q. Slow down.

MR. THORNBURGH: She needs to be able to record what you're reading.

THE WITNESS: Pardon?

MR. THORNBURGH: Just slow down.

Q. Slow down just a little bit.

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A. -- "that oxidative degradation was occurring in vivo cannot be taken seriously, given his lack of understanding of the formaldehyde protein encased polypropylene fiber."

That's laughable. I removed it. I showed you I removed it. Protein bands of amide I and amide II were gone. Figure 60, 61. That's laughable.

"Costello in his discussion section makes the following statements. The SEM micrographs displayed images of materials that were vastly different in topology in the pristine materials.

"The micrographs of explanted polypropylene materials exhibited cracks, surface roughness, and peeling indicative of surface degradation while the pristine materials appeared smooth.

"Once again, conclusions are being drawn with regard to SEM micrographs of polypropylene without any regard for the protein formaldehyde compounds at formation or any scientific evidence of a truly cleaned polypropylene surface."

Well, we showed you one, sodium hydrochloride cleaned. He's mixing up a lot of these gross techniques like GPC that dissolve the entire sample; DSC, which measures the melt point of the total sample, with techniques which are surface related. He's deliberately

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mixing that up.

And then he critiques Ostergard and he critiques me. I'll just take this down to make it simplified. He critiques everybody. So apparently he's the only person in the world who understands anything, including Nobel Prize winners. They don't count either.

"Reasons for concern and the supporting science follow: It's well-known that implantation of a foreign body, unless it's a foreign body reaction."

I agree with that.

"Formation of tenaciously adhered biofilm on the surface of implanted materials. It is most significant, and also well-known, that a high percentage of biofilm composition is proteins.

"All proteins possess carbonyl groups characterized by the following chemical composition," and he shows it. "Thus it is imperative that biofilm, and/or its chemical derivatives, be removed from mesh material before testing the explanted mesh."

I couldn't agree more. That's what we did. That's why we did it.

Q. What about your criticisms of Dr. Thames for the Bellew?

MR. THORNBURGH: Well --

A. Well, I can only respond to what he's saying

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here.

MR. THORNBURGH: I think what he's asking you, are those the major criticisms, without going through the entire report.

A. Yeah, that's a good sampling, I guess. I mean, he continues beating this protein coat to death. And I don't believe it for a minute. I've removed it and I still see oxidation. I still see it's polypropylene. It's the majority of the material.

So one of my major disagreements with him certainly would be that yes, there's protein there, but it's tissue, not biofilm as he calls it. You can't see it. It's an imaginary coating dreamed up by him. There is tissue there, and you can see the tissue. And you can clearly see the clean polypropylene either cracked or uncracked with the tissue in different spots.

Let's just pick an example. They're all over the place. So Figure 48, page 49. Now, this one is actually EDAX, but it's okay. It's Dianne Bellew A with mesh and tissue.

I'll just come over. Have you got it? That's in my report, sir. I'm referring to answering his question. Page 48. This is a typical example.

What I'm saying, Figure 48 -- what I'm saying is this is tissue, this is polypropylene. There is no

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biofilm here. And when you run the IR spectrum on this material, it's going -- we can go look at the other figure. We've already done that. It's polypropylene with some protein in it that's gotten in the cracks.

This is tissue, which is a majority of the polypropylene. And they're easily distinguishable. And when I run hypochlorite-treated samples, look how clean it is.

Q. We're talking about -- Hold on a minute.

So the record is clear, you're talking about Figure 36. It's your testimony that Figure 36 of your report, there's no tissue. Is that correct?

A. There's a couple little white specs which we believe are buffers or pieces of lint or something. But the tissue, like you see --

Q. But otherwise I'm correct?

MR. THORNBURGH: Objection.

A. This is clean polypropylene. Right.

Q. In Figure 36 before you?

A. 36. And this is the tissue dirty material in Figure 32 that hasn't been cleaned.

Q. Fine. Doctor, any other major disagreements with Dr. Thames's analyses in Bellew, or have we hit them all?

A. I'd have to go through them page by page. I

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don't know. There's so many of them. It got tiring. He keeps coming back, "However, the formaldehyde protein polymer is extremely difficult to remove from the mesh fibers."

No, it isn't. I watched it. I expected it was going to take hours. I did the Clave procedure with one step. In 15 minutes I couldn't even detect the protein on it any more, the tissue. It's gone. I watched it with my own eyes.

Q. And that was with the naked eye, Doctor?

A. That was. And then we looked at it by microscope as well, which I just showed you. By microscope, it was clean. LCM, it was clean. Optical microscopy, it was clean. Eyeball, it was clean. Clean, clean, clean.

Q. Doctor, I want to make sure I have all of the major criticisms that you have with respect to Dr. Thames' analysis for the Bellew case.

MR. THORNBURGH: You don't want his -- I'm going to object your word "major."

MR. HUTCHINSON: Make your objection.

A. "Prolene mesh and TVT-O degrades in the human body due to oxidation of the polypropylene." His response, "Absolutely no data exists to support this claim."

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Well, he's ignoring the molecular weight degradation. He's ignoring the carbonyl bands. He's ignoring the fact that it's cracked. It's like, I don't know, he's denying reality to me. I don't know.

"Analysis of the explanted fiber mesh by GPC. High temp indicated a large scale molecular weight degradation did not occur."

I agree with that. There's no bulk oxidation because, as I've said all day, the interior didn't oxidize. The exterior few microns did.

"Differential scanning calorimetry analysis of the explant fiber mesh and control samples showed a general trend of decreasing crystallinity for the cracked samples, demonstrating a larger portion of amorphous material in the cracked samples."

Q. Is that a major disagreement that you have with Dr. Thames?

A. Yeah, because he's going to say that -- I'm going to give you his response. Because he says -- his response, "Jordi report data do not provide predictive value in determining potential oxidation of Prolene explants."

And I said of course they don't. They provide predictive value of environmental stress cracking. He's trying to mix them up.

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So there's this major difference of opinion on additives. We measured it. It was lost. It was well protected. I would say that the inside might be fairly well protected because it isn't oxidizing at the same rate as the surface, but the surface clearly went. You can see it from the SEM.

Q. Doctor, have you personally ever done any cross-studies?

A. What?

Q. Have you personally ever done any cross-section studies of a TVT or a Prolift fiber?

A. Crawl?

Q. Cross-section studies.

A. "Crawl," is that the word?

Q. Cross, C-R-O-S-S.

A. Okay. Forgive my ears.

MR. THORNBURGH: Objection.

A. Cross-section. Yeah.

Q. Of the polypropylene fiber?

A. In some of these SEM graphs, you'll see ends cut.

Q. I'm not talking about the SEMs. I'm talking about any other tests or studies. Have you ever done any other tests or studies other than the SEM about the cross-sectional polypropylene fibers?

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MR. THORNBURGH: Objection.

A. I don't know what you're asking me, I guess. Cross-sectional --

Q. Have you ever studied --

A. We cut them and we analyzed them.

Q. And what did you find?

A. That's how we prepared the samples for our LCMS analysis and so on. The samples were taken out. They had to be cut.

Q. And would all of your tests or studies be reflected in your expert report?

A. Yes, sir.

Q. Dr. Jordi, before we move on, have we discussed all of the major criticisms that you have of Dr. Thames?

MR. THORNBURGH: Objection.

A. No. I'm only on page 23 of 100. Let's see. Page 23 of 88.

Q. I need to get all your major criticisms of Dr. Thames with respect to Miss Bellew.

MR. THORNBURGH: He's trying to tell you what they are.

A. "The Jordi report states, 'Figure 87, page 76, clearly shows the presence of a carbonyl band at 1761 and 1042 centimeters for the explanted mesh sample 13413.'"

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I say, "I disagree with this assignment" -- he says, "I disagree with this assignment. For instance, the 1761 carbonyl frequency is hardly discernable if it exists."

Apparently he can't see what your own people can see. I'll show you an example. This one --

Q. Doctor, in respect of our time, I want to get to the ETH MESH documents a little bit later.

A. Yeah, but that's part of answering this question.

Q. Okay.

MR. THORNBURGH: He's trying to answer your question.

A. So he says he can't see the frequencies. My point is, Ethicon's own people have no trouble seeing them. When I see a shoulder, he says it's invisible. When they saw a shoulder, they identify it. There's 1720. There's all kinds of them. There's another one at 1720. There's all kinds of them. What was that? 1759. They saw 1759, 60. There's more, but you get the point. They had no trouble seeing it. Only he does. My comment is maybe you should buy a new pair of glasses. I'm sorry.

MR. THORNBURGH: Maybe if you ask him do you criticize the majority of Dr. Thames's opinions, then

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that might streamline. Otherwise, we're going to be here past -- I'm suspecting past both of our flights.

A. Well, he says the same things here about Carol Lewis and Batiste and all of that.

Q. Let's focus on Bellew. I want to know your major criticisms of Dr. Thames's analyses with respect to Ms. Bellew.

MR. THORNBURGH: Keep on going, Doctor.

A. These are all -- you're talking about just Bellew now?

Q. Yes.

A. Because he's got --

MR. THORNBURGH: Have you read his report? He uses the Lewis data to criticize the Bellew data.

MR. HUTCHINSON: Dan, please stop talking. Make your objection and let's move on.

MR. THORNBURGH: Objection.

Doctor, continue to answer him the way you've been answering him.

Q. Just looking for major criticisms, Doctor.

A. He says here, "Contrary to the Jordi report claim, it is significant that the Jordi report" -- this is Carolyn Lewis and Batiste. I guess we can skip that.

Q. We can skip that, yes.

MR. THORNBURGH: Objection.

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Q. For Miss Bellew specifically, Doctor.

MR. THORNBURGH: Objection.

A. You don't care about my differences in any other area. Right?

Q. Right.

A. Good. Looks like we've picked back up on page 54. "Furthermore, hypochlorite treatment eliminated most of the protein (Jordi Bellew report, page 58)."

The response is, "However, the following statement, 'Once the amide I and amide II bands were removed using the sodium hypochlorite' . . . Are contradictory."

I'm not sure what he's talking about here. In fact, a portion of a protein was removed by sodium hypochlorite treatment yet some remained, as noted in the overlay spectra, Figure 61. I totally disagree with that. We went through it in great it length. Amide I and amide II bands are totally gone. Hence the protein is totally gone.

"Therefore, any further analysis of the Bellew, Dianne C explant must accommodate the remaining protein and residual chemicals."

So I put down here, you know, Figure 60 and 61 in the IRs that clearly show the protein is gone. Show

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the SEM micrographs, Figures 35, 36, 37, 40, 38, et cetera, which clearly show the tissue is gone, like I just showed you.

"Statement: In addition, the hypochlorite-treated Bellew sample showed all the characteristic carbonyl bands typical of oxidized polypropylene including aldehydes, ketones, and esters, as well as the COC band (Jordi Bellew report page 61)."

His response is, "According to Stuart, aldehydes show a CH stretching in the 2900 to 2700 reciprocal centimeter" --

That is actually laughable. Everything shows absorbance in the 2700 to 2900 range. Everything with a hydrocarbon, whether it's hexane -- well, benzene doesn't. Heptane. Your antioxidant would have bands there. Everything has bands there that has CH in it. So that's totally useless. I don't even know why he would make that statement.

"Esters, as characterized by fats and lipids, typically absorb in the regions of 1750 to 1730 and 13 00 to 1100."

That's the COC stretch. I agree with that frequency.

"As pointed out by Dr. Jordi, they are 'normal body chemicals.'"

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That's true.
"Moreover, calcium stearate, a fatty acid salt, and dilauryl thiodipropionate, possess carbonyl bands."
We've already been through that. They're too weak to see by infrared.
"And a COC band. And they are part of Ethicon's additives package."
They are initially, not after it leaches out.
"Thus, FTIR frequencies relied upon by Dr. Jordi as oxidation products of Prolene are accounted for as body derived chemicals and/or Ethicon's Prolene formulation additives."
But they're there at too low of levels to see, so I disagree with that.
"Finally, the Jordi report, page 63, states, 'A number of fatty acids as well as a series of compounds related to cholesterol were'" -- he has the same comments and I have the same answers, that they are at too low levels to see.
Q. Any other major criticisms with respect to Dr. Thames's analysis for Bellew, Doctor, that we haven't already discussed?
A. You'll have to tell me. I just got to go through and see what he says in each paragraph. I haven't got it memorized.

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Q. I need to know before we leave.
MR. THORNBURGH: Well, he's going through it, then. If you're going to try to make some motion later on, he's got to go through it.
A. This is the same idea. The idea, my comment is that these fatty acids and cholesterol, they're at too low level to say FTIR.
So he's got this whole argument about -- that the carbonyl groups is now from the fatty acids and cholesterol esters, which we disagree with for concentration reasons, being able to see any infrared. Not that we should not be able to see it in the infrared.
"From the composition of comparison of the formalin and hypochlorite treated exemplars and the untreated exemplar, it appears that formalin and sodium hypochlorite are able to partially extract/oxidize Santonox R."
I agree with that.
"It is possible that Santonox R in the Bellew sample was partially extracted during its storage in 10 percent formalin solution after explantation from the patient.
"Nevertheless, the relative quantitative data presented in Table 11 clearly shows that the levels of

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Santonox R in the Bellew explant sample is significantly lower that that of the formalin treated exemplar."
His response: "Jordi's control experiments wherein Prolene was placed in formaldehyde confirm significant extraction of Santonox R and to a lesser extent DLTDP from Ethicon's Prolene.
"In fact, a review of Table 2 will confirm formaldehyde, acting as a solvent to the explant, removed 55 percent and 75 percent respectfully as Santonox R from Prolene controls (Jordi report, page 74, Table 2, page 75). Yet they continue to use and report data generated via this process, in light of the extensive errors it promulgates.
"The Jordi data are definitive on this area; formaldehyde is an excellent solvent, in addition to its chemical reactivity, and extracts extensive amounts of Santonox R from Prolene fibers and lesser amounts of DLTDP. However, what remains unknown is whether formaldehyde also reacts chemically with Santonox R" --
I think we dealt with that earlier today.
Q. Right.
A. -- "and DLTDP to alter their chemical structure such that they would not and could not be identified by mass spectroscopy."
I don't know what he's talking about there.

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Well, if you change the chemical structure, it wouldn't change the raw additive. That's what he's driving at. And as I said, the DLTDP doesn't have a reactive function group to react with the formalin.
Now, I'm going to have to go to my section to answer this critique in my report. I got to go back to the LCMS section.
So if we go to Table 10, for example, if we look at page 73 -- let me know when you're there because I want you to see this.
Q. I'm there.
A. The Exemplar A -- This is for dilauryl thiodipropionate. We're not arguing that formalin doesn't touch Santonox R. We saw that flat out in the report. We are saying it doesn't seem to touch dilauryl thiodipropionate, the long-term stabilizer.
So Exemplar A gave 70 million-plus counts. Do you see that in Table 10?
Q. I do.
A. And Exemplar B, formalin treated, gave 68 -- essentially 70 million counts. Excuse me. 69 million counts. And Exemplar C, sodium hypochlorite-treated, gave 74 million counts. These are all extremely within experimental error.
Whereas the Dianne Bellew B sample without

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tissue gave 30,000-plus counts and the Bellew C sodium hypochlorite-treated gave 21,000 counts.

So we're down to about .04 percent of the additive left in the explanted material with no change in any of the others. Exemplar is the same as formalin treated is the same as hypochlorite treated. They're all within experimental error.

So his comment that we're extracting to a lesser extent dilauryl thiodipropionate makes no sense to me.

Now, there's another table if you want to go back. It's the same kind of idea. There's another table in the back. We can go through the other section for the other 22 samples, and it will show you the same answers.

Do you want to go through that?

Q. We do not need to do that. What other major criticisms do you have?

A. My statement was, "Based on the area counts for DLTDP in the three exemplars, it appears that formalin and sodium hypochlorite treatments have no major detrimental effect on the additive level present in exemplar fibers."

His response, "It is significant that the Jordi Lab DLTDP extraction time was two hours at 65 C whereas

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the Prolene explant was retained in formaldehyde for more than two years before Jordi Labs extraction and testing began.

"Simply put, formaldehyde had two-plus years to extract DLTDP before the Jordi Labs sample preparation began. There is no way to know how much DLTDP had been extracted and/or reacted with formaldehyde prior to Jordi Labs testing. If either occurred, the result would be reduction in DLTDP concentration."

Several criticisms. One, when you start extracting, it's an exponential curve. More of the material comes out first and then as time goes on you get less and less and less until you get full extraction, but the rate of extraction is slowing down.

So if we were going to get extraction, we did 65 days for 48 hours, which is equivalent roughly to a month at room temperature. It's accelerated extraction on purpose to see if we'd see anything.

So in the first month, we saw nothing. So my -- I mean, I didn't have two years to do this analysis. I did the best I could do with the time I had to work with. And it shows nothing for an extraction for DLTDP. It does show partial extraction of Santonox R.

Q. And, Doctor, when you say "partial," how would

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you quantify "partial"?

A. Well, the numbers are in the tables.

Q. Yeah. And how would you quantify the amount of extraction -- how would you quantify the amount of Santonox R that was extracted?

MR. THORNBURGH: Objection. Do you want to know the --

A. .04 percent is left, that means that point -- 99.6 percent is gone.

Q. No. We're talking .04 is DLTDP. Is that correct?

A. Yeah.

Q. I'm talking about Santonox R.

A. Well, we had -- I think we had 50-something percent. Those numbers, I agree with. And so that's in the expanded, sped-up process.

So in two years, I don't know. We're willing to give that to you. We just don't know. It certainly wasn't all out in a month at elevated -- I mean, the equivalent of a month at room temperature. And it's going to slow down. So I'm not convinced it's all going to come out.

Santonox R is the processing stabilizer, and DLTDP is the long-term stabilizer anyway. That's the one that concerns me in the body more than the other.

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But true, we were extracting some of the Santonox R. We give that to you. He is absolutely right on that.

So that's enough of that, I think.

On page 57, he's mixed up some of the numbers. He's misread -- I'll try to just explain this to you. He's misread the tables.

Q. On page 57?

A. Yeah. We can go through that and spend much more time.

Q. We don't need to spend much more time, if you just could show me what you mean by that.

A. Here is the principle. He's saying that formaldehyde is an excellent solvent for extraction. Well, he's lumping DLTDP and Santonox R together, which I just showed you doesn't fit because we saw nothing with the dilauryl thiodipropionate informally. It doesn't touch it, at least not in a month. So they're not the same, Number 1.

And then he says, "Exemplar C, sodium hypochlorite-treated control lost 75 percent of the antioxidant, Santonox R" -- that might be true -- "in the presence of these reagents. Formalin is a solvent and oxidizing agent. Sodium hypochlorite is an oxidizing agent." Yes, it is.

"In a similar fashion, Table 18 of the May 20,

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2014, Jordi report shows the control lot 3405404 propylene sample lost 12 percent of its dilauryl thiodipropionate simply by being immersed in formalin."

No, it didn't. He misread the table.

Do you want me to cover that?

Q. No. I think we've covered that.

MR. THORNBURGH: I think he's asking for -- I think what he's asking for is your general --

A. I'm ready to go on if you are. He misread the numbers.

Q. Okay.

A. It don't show any drop, as I showed you.

Q. Okay.

A. "Prior to discussions regarding individual spectral assignments, it's important to consider the following: the effects of the contaminated connective tissue on the infrared spectrum" -- sorry. Can you strike -- Well, strike it. I misread. I want to start over.

"Statement: Shoulder bands at 1740 to 1760 indicative of carbonyl groups" --

Q. What page are you on, Doctor?

A. 58.

Q. Okay. Top of page 58?

A. Yeah.

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Q. And what's your major criticism there?

A. Well, I'm just reading -- I got to read his criticism and then critique it. You can't understand a critique unless you know what he's critiquing.

"Absorption band at 1041 reciprocal centimeter region collectively are consistent with oxidation."

That's true. Well, that's my statement.

"Response: There are no shoulder bands in the FTIR spectra," and he goes on. And that's based on the same thing I showed you before. Everybody else from Ethicon can see it but him. And I can see it. They're shoulder bands. They're not individual bands:

"Statement: Once the amide I and amide II bands were removed using sodium hypochlorite, the FTIR revealed the underlying carbonyl oxidation bands from 1700 to 1760 with maximum at 1740, 1720, and 1710."

We went through that this morning.

"These frequencies are strongly suggestive of esters, ketones, and aldehydes respectively. All of these products are produced as a result of oxidation to polypropylene."

His response: "There is absolutely no proof that these frequencies are derived from oxidized Prolene."

That's why it didn't degrade. That's why the

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molecular weight is the same, and yet the melting point dropped precipitously in the nano-TA work.

We see the cracks in the SEM. We see the three carbonyls and the infrared. So I don't know what more information he needs. I don't know how I can disagree any more strongly.

Q. Any other major --

MR. THORNBURGH: You've already responded to the rest of that.

A. His attacks on the other work are the same as the attacks on Bellew.

MR. THORNBURGH: So you've already addressed the fatty acids.

Q. I agree with you on that. Any other major criticisms, Doctor, that you have of Dr. Shelby's analysis for Miss Bellew?

A. Well, we better cover nanothermal because that wasn't covered previously.

Q. All right.

A. That's at page 59.

Q. What are your major criticisms of Dr. Shelby Thames's analyses in the nanothermal section of his report beginning on page 59?

A. "In keeping with this comparisons, Figure 81 covers a width of approximately 1/7th of a human hair

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and a depth of 1/69th out of a human hair. Thus a question should be posed can a depression of only 1 micron truly be defined as a crack. For instance and by way of comparison, we have shown the thickness of the human hair measured at 69 microns."

They didn't measure the Bellew sample. So what they're comparing up here in their prior work is a different sample and comparing it to mine. I just -- the comments just don't make any sense.

"The Jordi report provides melting point data taken via the nanothermal AFM unit and states that the lowering of melting points via nanothermal analysis as opposed to DSC data confirm oxidation occurs on the surface."

I say it confirms degradation, not oxidation. Oxidation is one type of degradation. But we know it's degraded because its melt point dropped, which means its molecular weight dropped.

He says, "It is inappropriate and scientifically unfounded to make the following statement. Bellew, Dianne C treated with hypochlorite were also examined with AFM imaging and nano-TA. As can be seen from the AFM image in Figure 83, there is a significant difference between surface morphology between the Bellew, Dianne C and Bellew, Dianne C" --

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between B and C -- "fibers with large flakes of material visible on the surface of the hypochlorite treated."

And then he says, "To speak of large flakes when describing nanospatial relationships is nonscientific, confusing, and misleading."

I have no clue why. Why is it inappropriate to do this analysis? It beats me.

MR. THORNBURGH: Can we agree there are fundamental differences, both sides have criticisms, and so we can move on?

Q. Doctor, have we discussed all of the major criticisms you have with Dr. Thames in responding to the nanothermal analysis?

MR. THORNBURGH: Objection.

A. I think we're close.

Q. Okay.

A. Now he goes over the Burkley study, which we didn't care about, which is fine.

Q. Dr. Jordi, let's change gears for a minute. Are you ready?

A. You're directing it, sir.

Q. Thank you. Do you have any criticisms about the protocol used by Dr. Ong in cleaning the Bellew explant?

A. Well, let's go look at it. Do you know what

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page that is? It's in the back somewhere, I know.

Q. I'll give it to you in just a second.

MR. THORNBURGH: Page 76.

A. I was closing in on it.

MR. THORNBURGH: Objection.

Q. Any criticisms, Doctor?

MR. THORNBURGH: Objection. Dr. Ong hasn't even been deposed yet either, so there may be additional criticisms of both Dr. Thames and Ong after their depositions. So this exercise is --

MR. HUTCHINSON: Your objection is noted.

Q. Dr. Jordi, do you have any criticisms of the protocol used by Dr. Ong in cleaning the Bellew explant?

A. It seems to me to be extremely excessive. Since I used one sodium hypochlorite treatment and in minutes it looked clear, certainly the 26-hour test we could see nothing by SEM, optical microscopy or any other way.

To go through this whole tortured process to remove this imaginary protein coat that we can't even see -- we see tissue which is gone after one treatment. Why do we need all of this?

For sure in all the sonication steps that he's going through, he's shaking it to death, he's going to shake off the particles. So that when you're done --

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what he's really trying to do is shake off the cracked polypropylene so that the underlying undisturbed layer of polypropylene would be the only layer left. That's what I see this as doing. Not to do something that's gentle.

I would never use sonication on this where the material is already cracked via our SEMs. And if you're going to shake it to death, you're going to shake the particles off. It makes no sense at all to me.

Q. Any other criticisms, Doctor?

A. Why do you need four sodium hypochlorite treatments when one will do?

And then they also said the desiccation of drying causes cracking. Burkley said that and others along the way have suggested that in Ethicon's group. So they're going to desiccate it four times or -- I don't know, however many times it is there. 1, 2, 3, 4, 5, 6, 7. They do seven desiccation steps. Well, my goodness, if desiccation causes it to crack, they beat it to death, didn't they?

Q. Any other criticisms, Doctor? I need to know all your criticisms you have, sitting here today.

MR. THORNBURGH: Objection. Same objection.

A. I just see it as extremely excessive. It's something that I could do in one step, they couldn't do

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in 20 steps.

Q. Have we discussed all your criticisms about the protocol they used, Doctor?

MR. THORNBURGH: Objection.

A. Well, from this table at this time.

Q. Okay. Doctor, let's change gears for a minute and I want to talk about --

MR. HUTCHINSON: We can go off the record for just a minute, please.

(Recess taken)

BY MR. HUTCHINSON:

Q. Dr. Jordi, you have in front of you some ETH MESH documents that you've relied on in forming your opinions. Is that correct?

A. Well, I just received them yesterday. So I was in the process.

MR. THORNBURGH: Again, just for the record, these were recently produced to us for the first time -- for the record, we asked for the production of these documents and all documents like this related to degradation oxidation, et cetera, I think when this litigation began.

And the fact that we just now received these new documents after, what, at least two trials, another trial is about ready to begin, it's highly prejudicial

to our case. The prior cases and the cases that we've worked on up to date. That's my objection. Go ahead.

MR. HUTCHINSON: The objection is noted. Thank you.

BY MR. HUTCHINSON:

Q. Doctor, which documents have you relied on in forming your opinions and why?

MR. THORNBURGH: Objection.

A. Well, most of my opinions were formed before this. They just support my opinions which I had already formed.

So do you want me to list the ETH MESH numbers?

Q. I do. Please.

A. ETH MESH 15958452.

Q. Do you mind if I look over your shoulder?

A. No, not a bit. So I'm going to have to read. There's only a couple. There's not a hundred pages here, so it ain't going to take very long. It looks like it, but there isn't.

Q. I understand. For purposes of the record, if you just could read the last three digits, just the last three digits of the ETH MESH number of the documents that you relied on to form your opinion and why.

MR. THORNBURGH: Objection.

Q. And then I think we'll be done.

MR. THORNBURGH: He says these support his opinions, not -- you know what I mean.

Q. You can answer it, Doctor.

A. I'm just quoting now. It says, "In severe cases the cracks lead to the production of a separated layer of seemingly uniform thickness and relatively clean undersurface."

That's the bi-modal structure we've discussed all day.

"Also in severe cases secondary longitudinal cracks give rise to bricklike structures, Figure 3," and then they go into environmental stress cracking.

I agree with that, by the way.

"The reason for considering environmental stress cracking is that crazes always lead to cracks that form perpendicular to the direction of the applied stress.

"Subsurface crazes are known to occur at high degrees of extension in polymeric fibers. Polypropylene fibers have been shown to develop such crazes and elongations as low as 5 percent."

And that's what you would get when you make the bends in the mesh.

"One hypothesis is that if crazes are formed during application of the suture from overextension,

long-term exposure to a sensitizing agent in vivo may result in environmental stress cracking and the formation of micro cracks."

That's the cholesterol, cholesterol esters, and fatty acids, blah, blah, blah.

"The most effective crazing in stress cracking agents are those that have similar solubility parameters values to the polymer but are not solvents."

And that's why the hydrocarbony-type things are very similar, they're attracted to the polypropylene, and they are good agents.

"Medium length hydrocarbons, very similar to fatty acids and fatty compounds, come under this category and are known to be effective stress cracking agents for polyolefins.

"Oxidation. A great body of literature exists regarding" -- this was in 1984 -- "of the degradation of polypropylene in general as well as selective studies on the photo and thermal oxidation of polypropylene monofilaments.

"The cracking process in this case is chemical in nature rather than physical, such as environmental stress cracking. Transverse cracks form as a result of structural reorganization of oxidized polymer that has already undergone significant drops in the molecular

weight of the polymer."

We've shown that by our nano-TA. I couldn't agree more.

"Chain scission initiated by the incorporation of oxygen in the polymer takes place primarily in the amorphous phase of the polymer" -- that's the surface layer -- "due to oxygen solubility and mobility considerations.

"Cracking only occurs when stress bearing tie molecules and amorphous regions are severed. The retraction of the molecules into the crystalline regions takes place under the internal stress of the fiber. For this reason, the oxidized polypropylene generally exhibits an increase in density with a comitant increase in degree of crystallinity." That's initial.

"The oxidized polymer, however, is embrittled with losses of tensile strength and elongation," which flies directly in the face of what Dr. Thames has stated.

Q. Okay.

A. Now we go on to infrared?

Q. Yeah. And basically, Doctor, just for the record, this is page 454. And you're relying on the infrared paragraph. Is that correct?

A. Correct.

Q. All right. And, Doctor, you've also relied on the same page, the last part of the skin morphology paragraph. Correct?
A. Correct. And then we're going to rely on this on 455. I assume we'll get there.
Q. And you're also relying on page 455, the thermo-optical analysis about in the middle that begins, "If the cracked layer is oxidized," dash, "degradation polypropylene." Correct?
A. Correct.
Q. And, Doctor, on page 456, you've relied upon in support of your opinions the sentence under the electron micro-diffraction paragraph that states, "When viewed in the diffraction mode." Correct?
MR. THORNBURGH: Objection.
Q. You can answer.
Correct?
A. Yup.
Q. And, Doctor, on page 457 you've relied on some of the bullet points under "Discussion," including the last paragraph. Is that correct?
A. Yes.
Q. Doctor, anything else in this group of documents that you've relied on to support your opinion?
MR. THORNBURGH: Objection. Number 1, he never

received this because it was produced late to us.
MR. HUTCHINSON: Same objections apply. We understand.
MR. THORNBURGH: He doesn't have to tell you each and everything that he's going to rely on at the time of his deposition or trial testimony. He's going to rely on his paper.
MR. HUTCHINSON: I understand that. I'm asking what he's relied on.
Q. Doctor, you can answer.
Anything else?
MR. THORNBURGH: Objection.
Q. You can answer. Anything else?
A. Well, it's these yellow marked pages that I've got the infrared, the skin core morphology.
MR. THORNBURGH: Look at it and go through it.
Do you have to stand over his shoulder? You don't have a copy of this?
MR. HUTCHINSON: I don't.
A. "If the cracked layer is oxidized or," slash, "degraded of polypropylene, the molecular weight should be lowered."
And it is. That's what our nano-TA clearly showed.
"When viewed in a diffraction mode, the cracked

layer yields an amorphous halo while the fiber core produces a crystalline fiber pattern."
That's what Dr. Iakovlev showed as well, the two what he called the bark and the core.
On page 457, Bullet Point 2, "Transverse cracking in Prolene fibers may be induced by physical and chemical oxidation process," which is what I tried to explain. They work together in the environment in the body.
"Transverse cracks may be produced on Prolene sutures by environmental stress cracking of blemished surfaces as produced by abrasion during application." Another possibility.
Finally, they say under "Recommendations" on page 458, "Although the evidence presented tends to favor a biological origin for the micro-cracked layer, an additional study to either substantiate or disprove this hypothesis should be done."
And they did do it. And that's the point being a lot of their comments here were hypothesis, which they followed up with a later report.
Q. And this later report you're referring to is November 13, 1984, the last three digits of the ETH MESH number is 336. Correct?
A. Yup.

Q. And, Doctor, if I could have just a chance to glance through this.
(Pause)
Q. Doctor, how long have you spent studying these documents that have been marked as collective Exhibit 4?
A. I don't know. An hour or two.
Q. Doctor, can we actually --
MR. HUTCHINSON: Miss Court Reporter, can we have a color copy of this November 13, 1984, memo along with the specific pages that are tabbed.
THE REPORTER: Sure.
Q. And then, Doctor, the last document in this exhibit is labeled ETH MESH 462. Correct?
A. Correct. Let me look at it. Okay.
Q. And as I understand, you've only highlighted one paragraph in this document. Is that correct?
A. Maybe one or two more.
Q. One or two. You're correct. And the first paragraph is on 462. It's the paragraph that starts, "The average breaking strength."
A. That's right.
Q. And the second paragraph was on page 454. It states, "It is obvious that the severity of cracking is related to the implantation time." Correct?
A. Implantation time. Yeah.

Q. Anything else?
A. I don't think so.
So with regard to page 462, they're saying that "The average breaking strength remaining for size 30 was 76 and a half percent, range 47 to 93 percent. For size 40, it was 98.25 percent range, 86 to 110 percent when compared to similar sized controls.
"Only one length of 50 Prolene was available for tensile strength measurement, indicating 76 percent strength remaining for the seven-year specimen."
So this is -- this just flies in the face of what Thames was saying about the sutures where the tensile strength increased. Here, it went down. But -- And that's why I said his were sutures. These are fibers. So the type of material used apparently has an effect.
And this is just something we basically all agree on. It is obvious that the severity of cracking is related to the implantation time. It is obvious. 454 -- page 454.
Q. Okay.
MR. HUTCHINSON: Let's take a quick break.
(Recess taken)
BY MR. HUTCHINSON:
Q. Dr. Jordi, one final question. On Exhibit 4,

there are in essence three sets of documents. Is that correct?
A. Yes.
Q. And you'll agree that they are highlights on certain pages of these documents. Correct?
A. Right.
Q. Who made those highlights?
A. I did.
Q. Anybody else?
A. No.
MR. THORNBURGH: You've already asked these questions earlier.
MR. HUTCHINSON: I don't have any more questions. Thank you for your time.
MR. THORNBURGH: I've got some questions.
EXAMINATION
BY MR. THORNBURGH:
Q. Dr. Jordi, I'm going to try to do a professional courtesy and get defense counsel out of here as quick as possible, but I've got some questions I've got to ask.
A. Yes, sir.
Q. First off, did defense counsel ask you any questions regarding your opinions from the later study, the November 13th, 1984, study?

A. No.
Q. Doctor, in the November 13th -- I'm not going to go through this entire document because I know it's huge or it's large.
In this November 13th, 1984, study that's part of Exhibit 4 with ETH MESH Number 15958336, first off, this study came after the November 5th, 1984, report. Correct?
A. Right.
Q. Doctor, what did -- summarizing briefly, what did Ethicon's scientists determine in regards to whether or not the Prolene can degrade through the oxidation process?
MR. HUTCHINSON: I object to form.
A. Well, under ATR experiments, they say clear evidence of protein was observed. And then I see this band at 1714, which is not observed in spectrum of serum protein. They say it's characteristic of oxidation.
Q. Was the overall conclusion that the polypropylene can degrade -- the Prolene -- Ethicon's Prolene can degrade through the process of oxidation?
MR. HUTCHINSON: I object to form.
A. Well, what they're saying here is that the -- yes, it degraded the -- they're saying here when the protein coat was removed, microscopic examination

revealed that the cracking remained. Hence, it was -- the cracked material was polypropylene.
Q. Doctor, do you remember we went through Dr. Thames's -- Dr. Thames's expert report regarding this protein formaldehyde cross-link polymer that encases the outer layer of the Prolene? Do you remember that discussion?
A. Yeah.
Q. Did Ethicon's scientist in this study try to determine whether or not formaldehyde or formalin will have a reaction with the protein that will change the -- chemically change the composition of the Prolene fibers?
A. Well, they say the ATR spectra obtained, Figure 78, show -- without reading it, it's hard.
Q. Let me point you to --
A. They say, "When a protein coat was efficiently removed from the surface and the protein-coated version Prolene using soluene, no spectral evidence of soluene remained."
Q. Let me try to direct you to --
A. The cracking remained, so it's polypropylene.
Q. If you turn to page 4, ETH MESH ending in Number 339.
A. Okay.
Q. Do you see where it says, "The series of

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polypropylene film experiments were done to"? Do you see that?
A. Yes.
Q. What is -- I'm not going to go through all these because we -- I think we've talked about all of these enough. I'm going to ask you some questions that defense counsel didn't ask you regarding this document.
What does Number 3 say part of this test was intended to do?
A. Well, "Verify that formalin does not react or alter the polypropylene explants."
Q. And it says -- And explants would be explants that would contain protein potentially on it. Correct?
A. Right.
Q. And what was Ethicon's scientists' conclusions in 1984 regarding this protein polymer or protein formaldehyde polymer that Dr. Thames has?
A. Well, "Formalin solution appears to have little effect on the oxidized polypropylene surface and no effect on the surface with soluene."
It's totally removed, soluene, they say, and all that's left is polypropylene. Oxidized polypropylene. Excuse me.
Q. And that's contrary to Dr. Thames's opinions in this case, the Corbett case, and all the other cases

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where he's testified. Correct?
MR. HUTCHINSON: Objection. Leading.
Q. Does that statement -- that scientific statement contradict Thames' and Dr. Ong's opinions in the Bellew case, the Corbett -- the New Jersey cases, and every other case where he's testified in this litigation?
A. Yes. Because he claims he needs 20 steps to remove it. They just use soluene and it was gone in '84. All of a sudden he needs 20 steps today to do the same thing.
Q. Does this statement contradict Dr. Thames's and Dr. Ong's opinions concerning the protein formaldehyde polymer that would, according to them, encase the outer fibers of the mesh?
A. They use soluene to remove the protein, and they said formalin solution has no effect.
Q. Did they find any chemical reaction between the formalin and the protein on the oxidized polypropylene?
A. It has no effect is what they say.
Q. Ethicon knew that in 1984?
A. '84.
MR. HUTCHINSON: Objection. Leading.
Q. When did Ethicon learn that there is no chemical reaction between protein and formalin on the

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oxidized polypropylene?
MR. HUTCHINSON: I object to form.
A. It was reported November 13, 1984.
Q. Would that document have been important for you to have when testifying in the Batiste trial, the Lewis trial, and the other depositions that you've given in this case?
A. It certainly was relevant data that was apparently withheld.
Q. Does this document support your opinions in this case?
A. Yes.
Q. Do they contradict the defendants' opinions in this case?
A. Yes.
Q. I'm not going to go over everything because you've been here a long time, but let me ask you this question: Do you remember being asked questions about the nano-T study that you did in this case?
A. Yes.
Q. And nano-TA would be -- the TA would be thermal analysis?
A. That's right.
Q. How long has thermal analysis been around in the scientific community?

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A. Longer than I've been alive. It's been around probably since the late 1800s, the melt point and that kind of thing.
Q. Melt point analysis has been around for longer than -- older than your age?
A. For sure that.
Q. How long have you been -- have you performed melt point analysis or thermal analysis in your career?
A. From Day 1.
Q. Is it fair to say that for at least 35 years --
A. Yup.
Q. -- you've been performing melt point analysis?
A. Yes.
Q. And is that the same type of analysis that you did when you did the nano-TA analysis in the Bellew case?
A. The same type.
Q. The same -- based on the same scientific principles?
A. The same scientific principles, the melt point.
Q. And did you rely on -- in addition to that, your background, training, and experience in thermal analysis, did you rely on peer-reviewed, published publications regarding nano-TA and polypropylene?
A. I did.

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Q. And are those identified in your expert report?
A. They're in the report.
Q. Doctor, do you remember when Mr. Thomas asked you some questions about who performed which tests that were done and reported in your expert report, which person or company performed which tests?
A. Yes.
Q. Is it standard in your industry to have other labs analyze samples?
A. Absolutely is, from the biggest to the smallest.
Q. In fact, do other labs from time to time send you their samples -- despite the fact that they have a polymer lab, send you samples to analyze?
MR. THOMAS: I object to form.
A. Yes. For example, Evans is -- I don't know -- about a $7 billion company. They send LCMS samples to us.
Q. Have medical-device manufacturers -- have they sent you medical devices to analyze, despite the fact that these medical-device companies have labs within their company?
MR. THOMAS: Objection.
A. Probably represents -- it certainly represents the majority of our business, probably 75, 80 percent.

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I don't know what the exact percentage would be.
Q. Since I have an objection, let me try to ask a better question.
Have you received medical devices from medical-device manufacturers to analyze?
A. All the time.
Q. Are you aware whether or not some of these medical-device companies have their own polymer labs, such as Ethicon, but send you their products despite having labs?
MR. THOMAS: I object to form.
Q. Let me ask a better question because I don't want to indicate Ethicon.
Are you aware whether or not the medical-device companies who send you samples to analyze, whether some of those companies have their own labs?
A. I would think virtually all of them do.
Q. Do you have personal knowledge of whether or not some of them have --
A. Some of them definitely do. I've been in them.
Q. So is it standard not only in the polymer industry but also in the medical-device manufacturing industry to have other scientists perform lab work outside of their facilities?
A. Yes.

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Q. Do you remember when Mr. Thomas asked you questions like who conducted the DSC?
A. Right.
Q. Is it standard in the polymer industry to have technicians conduct the lab work in the polymer industry?
A. Yes.
Q. Did you interpret the data -- as the polymer scientist, did you interpret all the data that is related to either the Bellew or the Corbett New Jersey report?
A. Yes.
Q. And are your opinions in this case, the Corbett or the New Jersey cases and the Bellew cases, your opinions? In other words, did you rely on anybody else's opinions or did you formulate your own opinions based on your analysis of the data?
MR. HUTCHINSON: Objection.
A. Analysis of data, reading the technical literature, and my 40 years of experience.
Q. Do you remember being asked a few questions about the Corbett report or the New Jersey report?
A. Yes.
Q. Based on -- I want to ask the question a little bit differently because Dave didn't, I don't think, ask

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a complete question.
Based on your review of the scientific literature, your review of Ethicon's internal documents, your own data that you've produced from your review of the other 24 explants, based on your knowledge, training, background, and experience, do you have an opinion to a reasonable degree of scientific certainty whether or not it is more likely than not that the Corbett and New Jersey plaintiffs' mesh devices would have oxidized and/or underwent environmental stress cracking causing degradation?
MR. HUTCHINSON: I object to form. Also move to strike counsel's comments at the beginning of the question.
A. Do I have an opinion?
Q. Do you have an opinion based on all those things I just mentioned -- your background, training, and experience, your review of the scientific peer-reviewed literature, your review of the internal Ethicon documents -- whether or not to a reasonable degree of scientific certainty Miss Corbett's mesh degraded while inside her body?
MR. THOMAS: I object to form.
A. More likely than not, certainly, because of the vast majority of samples degrade.

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Q. And would that opinion be the same for other plaintiffs in the New Jersey case whether or not you've had a chance to review their -- any explants?
MR. HUTCHINSON: Same objection.
A. Based on the analysis of all of the samples, it's more likely than not that they've degraded.
Q. Based on your review of Ethicon's internal documents and your own data, do you have an opinion to a reasonable degree of scientific certainty whether or not the antioxidants would leach out of polypropylene meshes generally, Prolene mesh in general?
MR. HUTCHINSON: I object to form.
A. I do. And they do.
Q. And did you also have an opportunity to review the deposition of Dr. Thomas Barbolt?
A. I did.
Q. What did Thomas Barbolt testify to regarding whether or not the antioxidants leach out of the Prolene in the TVT and TVT-O meshes?
MR. HUTCHINSON: I object to form.
A. He testified that it leached out.
Q. Did you read any internal documents of Ethicon where they also performed melt point analysis of explanted Prolene products?
A. Well, I think 1918, page 248, showed that it

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melted from something like 147 to 156.
Q. And did Ethicon --
MR. HUTCHINSON: I'm sorry, Dan, but you said the 1918 --
THE WITNESS: Yeah, it's here.
MR. THORNBURGH: It's in prior depositions.
MR. HUTCHINSON: I didn't know if he was -- I didn't know if it has already been marked as an exhibit.
A. It was here in my pile this morning. Is it buried underneath this now? It was here. I know it was. It's just a one-pager. That's all the SOP, so that can't be it.
MR. HUTCHINSON: Okay. Gotcha.
MR. THORNBURGH: I don't know if that was marked. Is that marked as part of 4? Let's go ahead and mark it.
MR. HUTCHINSON: Let's make a note on the reference that document bearing Bates Number Depo ETH MESH 00000367 is included within Exhibit Jordi 4.
MR. THORNBURGH: We'll go ahead -- Okay. That's fine.
A. That's part of the document. Sure.
Q. And what document do you have in front of you right there? What's the Bates number on that one?
A. ETH MESH 00004755.

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Q. And what does that document appear to be?
A. Guidoin explant samples.
Q. Okay. And can you describe that document a little further for the ladies and gentlemen of the jury and the court? What's it showing?
A. It's showing explanted samples and the cracking, severe cracking, middle cracking, severe surface cracking. It just describes the cracking levels on each sample that was explanted.
Q. Just like your own data, did Ethicon's own scientists determine that the majority of mesh explants degrade?
A. Yes, the majority of these samples degraded.
Q. And was this explant that's discussed in ETH MESH ending in 00000367, is this explant in this exhibit from this 1918 part of those explants that Guidoin provided?
A. Yes, it's part of that. And the melting point I'm referring to is of an eight-year implant, 83-D 035, which had severe cracking.
Q. In that study by Ethicon regarding that explant suture, did Ethicon's scientists determine whether or not the Prolene mesh had degraded as a result of oxidation?
A. Well, I'll quote. "The surface of some of the

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83-D 035 explants were scraped off with a needle. The cracked surface came off easily. It had the appearance and handling of a waxy snow. Melting point of the surface material was 147 to 156 C."
This is in the realm of degraded Prolene. Prolene melts approximately 155 to 165.
Q. And do you remember seeing additional Ethicon studies regarding that mesh -- I'm sorry -- that Prolene product where they determined that the DLTDP will leach out over time and that the cracked surface that was tested in this study lacked DLTDP?
A. I think the Barbolt deposition said -- are you talking about these?
Q. Yeah. You don't have them with you. I think maybe -- I think I saw it in the report, on page 11 of your report.
A. Okay. Describing the Guidoin samples we were just looking at, I believe, or very similar.
Q. You go on and say, "Ethicon scientists performed melt point and FTIR studies on two, two-year explants and had" -- "that had no visual evidence of cracking on an eight-year explant that had visual evidence of severe cracking on an unused pristine control."
And then you describe Dan Burkley's conclusions

there.
A. I describe the amount of DLTDP is reduced.
Q. Did Ethicon's own scientists determine that the amount of DLTDP, the antioxidant that we've been talking about today, is reduced over time during the implant time?
MR. HUTCHINSON: I object to form.
Q. What does Number 1 say in Mr. Burkley's conclusions?
A. "The amount of DLTDP is reduced in the explanted sutures. No DLTDP is observed in the surface scraped or cracked regions of the 83-D 035 sample."
That would be the eight-year implant sample.
"The observed DLTDP decreases with implant time."
Q. Is that consistent with your own opinions?
A. Yes.
Q. And then Number 3 says, "The surface scraped materials from the cracked regions has a melting range indicative of degraded polypropylene."
Is that consistent with your own opinions?
A. Yup. Yes. I think it's also instructive that he says no protein is observed in any spectra of the explanted sutures.
MR. HUTCHINSON: Move to strike as

nonresponsive.
MR. THORNBURGH: I think I'm done. I'm just looking -- I do -- I'm going to finish. But I failed to give this to you earlier. I just wanted to make sure the record was clear. I don't think this was part of what we produced earlier, but this is the billing expenses related to the New Jersey litigation Corbett cases.
MR. HUTCHINSON: Relating to what, the Corbett cases?
MR. THORNBURGH: The New Jersey cases. I don't know if it -- I think it relates to all of the Corbett -- the Corbett report. Sorry. Strike that. The New Jersey report.
MR. HUTCHINSON: Why don't we ask him.
FURTHER EXAMINATION
BY MR. HUTCHINSON:
Q. Dr. Jordi, I want to hand you what's been marked or what I'll have marked as Exhibit 16 to your deposition.
(Exhibit Number 16
marked for identification)
Q. Will you tell me what that invoice represents, please?
A. Billing time for consulting. So what's the

date on this? 5/30. So it would have been New Jersey cases.
Q. And what New Jersey cases specifically would that include?
A. I don't have the list in front of me.
Q. Where would the list be?
A. I suppose Chris would have it. In fact, there were no samples received anyway for any of this.
Q. For any of the New Jersey plaintiffs?
A. I don't see --
Q. For any of the New Jersey cases. Correct?
A. Right. I never got any samples for them. So it's hard to remember something I never saw.
Q. Dr. Jordi, does this represent your fees and expenses or just fees?
A. Well, we had -- I don't think there were any travel expenses in that particular case, just like there won't be for today. I didn't have any travel here. But there will be consulting.
Q. Exhibit 16, does this represent only your fees?
A. The $350 an hour says it's fees.
Q. And it has no expenses on there. Correct?
A. No, it does not.
MR. HUTCHINSON: Thank you. I don't have any more questions. Appreciate your time, Dr. Jordi.

(Exhibit Number 15
marked for identification)
(Whereupon the deposition was concluded at 4:36 p.m.)

COMMONWEALTH OF MASSACHUSETTS
SUFFOLK, SS.

I, Michelle Keegan, Registered Merit Reporter and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that HOWARD JORDI, PH.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record, to the best of my ability, of the testimony given by the witness.

I further certify that I am neither related to nor employed by any of the parties in or counsel to this action, nor am I financially interested in the outcome of this action.

In witness whereof, I have hereunto set my hand and seal this 25th day of August, 2014.

Notary Public
My commission expires:
May 16, 2019

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
HOWARD C. JORDI, PH.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.

My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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